
Capitolo E. Specific Guidance on Content of IUCLID Sections

This chapter provides specific guidance on the content of all IUCLID sections and subsections, which includes guidance on all data entry fields. The instructions on Endpoint study records of sections 4 to 10 are completely based on the help texts provided with the OECD Harmonised Templates (see chapter D.4.7.1 What is an Endpoint study record?).

All help texts are accessible as context-sensitive online Help by selecting the Help button  on the toolbar or pressing the F1 key on the keyboard (see chapter A.3 Online Help).

Nota

Section *0 Related information* is actually not a data entry section, but gives an indication of all associations existing between a Substance dataset and Templates, Categories and Mixtures. In Substance datasets, the following subsections are provided:

- Section *0.1 Templates*: So-called Inherit Templates can be added to a dataset and are then indicated as links (i.e. Template datasets serving as containers for Endpoint records which are "inherited" to a dataset). In addition, Endpoint records can be copied from so-called Copy Templates. For detailed guidance, see chapter D.5 Template (Create and update Template related information).
- Section *0.2 Categories*: Links to all Categories are provided which the Substance dataset under consideration is related to as member of these chemical categories. For detailed guidance, see chapter D.6 Category (Create and update Category related information).
- Section *0.3 Mixtures*: Links to all Mixture datasets are provided which the Substance dataset under consideration is related to as a component.

In Mixture datasets, the following subsections are provided only:

- Section *0.1 Templates*: as above.
- Section *0.4 Related Substances*: Substance datasets related to the Mixture as components can be added and are then indicated as links. For detailed guidance, see chapter D.7 Mixture (Create and update mixture related information).

For more information, see chapter D.4.6 How to manage sections 0 - 3.

1. [1] General Information

This section covers:

- Identification, composition and analytical information of the substance.

- Identifiers of the substance.
- Information on Joint submission.
- Information on Suppliers, Sponsors and Recipients.
- Specific information on Product and Process Oriented Research and Development (PPORD).

1.1. Identification

Chemical name: The name of the Substance dataset given by the user when he created the dataset is displayed. If necessary, this name can be changed by clicking the **Wizard** button .

Nota

The Substance dataset is identified by its chemical name given when the dataset is created. Any chemical identifier can be used. It is however suggested to select an identifier which is commonly used for that substance within the company. This can be for instance an internal name or a CAS number.

Legal entity flag: Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Legal entity: The Legal entity name owning the Substance dataset and assigned during the creation process of the dataset is displayed. The **Goto** button  allows to directly access the Legal entity stored in the Legal entity inventory, where it is possible to add or modify the information. All modifications will be automatically updated by clicking the **Save** button . The **Back** button  button will lead back to section 1.1 Identification.

Nota

The **Wizard** button  allows changing the Legal entity owner of the substance (see chapter D.17 user management). It is not possible to create a Substance dataset without establishing a relation to a Legal entity assigned to the current User account.

Third party flag: Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Third party: Indicate the name of the Third party representative appointed by the Company/organisation. Click the **Link** button  to select the Third party representative and establish the link. If the desired Third party is not present in your database, click the **New** button. It will trigger the opening of the Legal entity creation dialogue. Follow the instructions as described in chapter D.9.2 Feature "Legal entity - New": How to create a Legal entity). The Legal entity of the Third party representative 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  and follow the instructions given in chapter D.9.3 Feature "Legal entity - Update": How to update (edit) a Legal entity). The

modifications will be automatically updated by clicking the **Save** button . The **Back** button  button will lead back to section *1.1 Identification*. The link can be deleted by clicking the **Delete** button .

Nota

The Third party is the point of contact to represent the Legal entity in all aspects of data sharing under the REACH regulation.

Role in the supply chain

Role flags: Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Role: Select the role of the Legal entity in the supply chain for the Substance under consideration.

Nota

More than one role can be selected, however certain roles are exclusive: A manufacturer can also be an importer and/or an only representative at the same time, but cannot be also a downstream user. A downstream user cannot simultaneously be a manufacturer, and/or importer, and/or only representative.

- **Manufacturer:** The manufacturer is any natural or legal person who manufactures a Substance (in the EU under REACH).
- **Importer:** Any natural or legal person who is responsible for import (in the EU under REACH).
- **Only representative:** Any EU-based representative of a non EU-manufacturer. (The "only representative" needs to have sufficient background in the practical handling of substances and information related to them. The only representative has to be designated by the non-EU manufacturer). The official assignment documentation from a non EU manufacturer may be indicated in chapter *1.8 Suppliers*. 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 specified in chapter *1.8 Suppliers*.
- **Downstream user:** Any natural or legal person other than the manufacturer or the importer or the Only representative, who uses a Substance.

Nota

The importer of a substance which is exported from the European Union, and re-imported into the same supply chain is considered to be a downstream user.

Reference Substance

Specify the Reference substance for fully identifying the Substance under consideration. This is done by creating a link with the desired Reference substance element stored in the Reference substance inventory (see chapter D.11 Reference substance (create and update Reference substance related information)).

Click the **Link** button  to select the Reference substance and establish the link. If the desired Reference substance is not present in your database, click the **New** button. It will trigger the opening of the Reference substance creation dialogue. Follow the instructions as described in chapter D.11.4 Feature "Reference substance - Update": How to update (edit) a Reference substance. The Reference substance is created and simultaneously linked to the Substance dataset.

To complete the information of this newly created Reference substance, click the **Goto** button . The modifications will be automatically updated by clicking the **Save** button . The **Back** button  button will lead back to section 1.1 *Identification*. The link can be deleted by clicking the **Delete** button .

Nota

Only active Reference substances can be assigned.

Nota

For Mixture datasets, the link to a Reference substance cannot be created in the identification section, but only in the Composition section where identification of the components of the Mixture is done.

Type of substance

Composition: Indicate the type of the substance by selecting a value in the picklist. Picklist options: || mono constituent substance || multi constituent substance || UVCB || polymer || other: ||. If none of 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.

Origin: Define the origin (or the status) of the substance, using the picklist. Picklist options: || element || inorganic || organic || organometallic || petroleum product || other: ||. If none of 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.

Trade names

Role flags: Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Name: Insert all commercial names or trademarks by which the substance is known. For each entry add a new row in the table by clicking the green **Plus** button .

Contact person

Insert all information related to the person responsible for the Substance and the future Dossier to be submitted. The following fields are available:

Role flags: Set the confidentiality flag and regulatory purpose.

Organisation: Name of the organisation.

Department: Name of contact person (e.g. Scientific Department).

Title: Title of the contact person (e.g. Mr.).

First name: Of the contact person (e.g. Henri).

Last name: Of the contact person (e.g. Smith).

Phone: Of the contact person (e.g. 39 332 785241).

Mobile: Of the contact person.

Fax: Of the contact person (e.g. 39 332 785240).

E-mail: Of the contact person (e.g. henri.smith@legalentity.it).

Address: Enter the address of the contact person (e.g. Umkomaas Road 28).

Address: Use this second address line, if necessary.

Postal code: Enter the postal code (e.g. 01234).

Town: Enter the town.

Region/State: Enter the Region/State of the contact person.

Country: Select the country in which the contact person is located 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.

Remarks: If necessary provide any additional comments here.

1.2. Composition

A Substance is defined by its composition. The composition of a Substance can consist of constituents, impurities and additives. **This section is a repeatable block section.** It enables to enter multiple compositions for a Substance, e.g. to allow different profiles of impurities provided it does not change the identification

of the Substance. For detailed instructions on how to define the substance composition in IUCLID, see chapter D.4.1 Substance (create and update substance related information)

Substance composition

Click the green **Plus** button  to open the repeatable block. If more than one Substance composition has to be specified, add a new block for each composition.

Name: The name field gives the possibility to make the distinction between the different compositions, in case there is more than one. Select a name representative of the composition (e.g. degree of purity). If there is only one composition, the name of the substance can be filled in this field.

Brief description: Enter a brief description of the substance if appropriate.

Degree of purity

Set the confidentiality flag and regulatory purpose.

Indicate the degree of purity (or the appropriate range); give the typical percentage purity with the upper and lower limit for typical commercial batches of the substances.

Nota

For REACH purposes specifying only the degree of purity is not sufficient. The composition of the substance has to be fully described.

Constituents

This part is a repeatable block subsection enabling to provide detail on all constituents of the substance. Click the green **Plus** button  to open the repeatable block. If more than one constituent has to be specified, add a new block for each constituent.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Reference substance: Specify the Reference substance for fully identifying the constituent under consideration. This is done by creating a link with the desired Reference substance element stored in the Reference substance inventory. Click the **Link** button . If the constituent is not present in your database, click the **New** button and proceed as described in chapter D.11.3 Feature "Reference substance - New": How to create a Reference substance.

Proportion (typical): Give the typical purity percentage of the Substance. If the Substance is a multi-constituent substance, give the typical percentage purity with upper and lower limits for each of the main constituents.

Proportion (real) : Give the percentage of the component(s) with the upper and lower limit.

Remarks : If necessary provide any additional comments.

Impurities

This part is a repeatable block subsection enabling to provide detail on all impurities of the substance. Click the green **Plus** button  to open the repeatable block. If more than one impurity has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Reference substance: Specify the Reference substance for fully identifying the impurity under consideration. This is done by creating a link with the desired

Reference substance element stored in the Reference substance inventory. Click the **Link** button . If the impurity is not present in your database, click the **New** button and proceed as described in chapter D.11.3 Feature "Reference substance - New": How to create a Reference substance.

Proportion (typical): Give the typical purity percentage of the impurity.

Proportion (real) : Give the percentage of the impurity, with the upper and lower limit.

Remarks: If necessary provide any additional comment.

Additives

This part is a repeatable block subsection enabling to provide detail on all additives of the substance. Click the green **Plus** button  to open the repeatable block. If more than one additive has to be specified, add a new block for each one.

Nota

Additives in the REACH regulation are stabilising agents, necessary to preserve the substance stability. Thus, additives are an essential constituent of the substance and are taken into account, when making the mass balance.

Outside the definition of REACH the term "additive" is used for intentionally added substances with other functions, e.g. pH-regulators or coloring agents. These intentionally added substances are not part of the substance as such, and for REACH they are not taken into account, when making the mass balance. Preparations, as defined in REACH, are intentional mixtures of substances and are consequently not to be considered as multi-constituent substances.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Reference substance: Specify the Reference substance for fully identifying the additive under consideration. This is done by creating a link with the desired

Reference substance element stored in the Reference substance inventory. Click the **Link** button . If the additive is not present in your database, click the **New** button and proceed as described in chapter D.11.3 Feature "Reference substance - New": How to create a Reference substance.

Proportion (typical): Give the typical purity percentage of the additive.

Proportion (real): Give the percentage of the impurity, with the upper and lower limit.

Remarks: If necessary provide any additional comments.

1.3. Identifiers

A series of Substance identifiers can be added in this section, e.g. Registration numbers assigned by European Chemicals Agency when the registration dossier is considered as complete or internal company identifiers making the link with other IT systems (for example SDS system ...).

The following tables are formed of repeatable blocks of fields displayed in table-view format. Click the **Add row** button  to enter a new row.

Regulatory programme:

Tabella E.1. Regulatory programme

Flag	Set the confidentiality/regulatory purpose information.
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.
ID	Insert the identification number distributed by different regulatory programmes (e.g. the REACH registration number).
Remarks	If necessary, provide any additional comments here.

IT system identifiers

Tabella E.2. IT system identifiers

Flag	Set the confidentiality/regulatory purpose information.
Regulatory programme:	Specify the IT System identifier (e.g. IUCLID 4)
ID	Insert the corresponding identification number.

Remarks

If necessary, provide any additional comments here.

1.4. Analytical information

Analytical methods and spectral data

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Analytical methods and spectral data: Report the description of the analytical method(s) used and provide appropriate spectral data. Sufficient information should be given to confirm the structure of the substance.

Spectral data files can be attached to this section by clicking 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.

Nota

Sufficient spectral data are needed to confirm the structure of the substance. One or more of the several spectroscopic methods that are suitable for the specific class of substances may be used (UV/VIS, infra-red, nuclear magnetic resonance or mass spectrum). A chromatogram can be given to confirm the composition of the substance, if applicable. If appropriate, also other valid constituent separation techniques might be used. For those substances for which spectral data, GC or HPLC chromatograms are not sufficient for identification, information resulting from other analytical techniques can be given, e.g. X-ray diffraction for minerals, elementary analysis etc.

Optical activity: Describe the optical activity of the substance.

Result of analysis

This part is a repeatable block subsection enabling to provide detail on all results of the analysis done on the substance. Click the green **Plus** button  to open the repeatable block. If more than one result has to be specified, add a new block for each one.

Analysis type: In this section report the type of analysis.

Tested substance: Report the tested substance.

Method used: Describe the method used.

Add documentation by clicking 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.

Remarks: If necessary provide any additional comments here.

1.5. Joint submission

This part is a repeatable block subsection. It enables to specify different groupings of Companies to prepare Joint submission registration dossiers under REACH and consortium dossiers for the OECD HPV Chemicals Programme.

Under the REACH regulation, Companies have to share information on the same substance. One of them acts as the Lead, i.e. he is responsible for submitting on behalf of the other registrants information on the intrinsic properties of the substance and its effects on the environment and human health (i.e. (robust) study summaries) and the classification and labelling. He may also be in charge to submit information on guidance on safe use and the Chemical Safety Report.

The lead Legal entity creates the joint submission in his local IUCLID installation and therefore needs to request from the other participants their Legal entity information so that data consistency may be ensured between IUCLID installations. Each participant exports his own Legal entity object and sends the export file electronically to the lead Legal entity.

It is recommended that all other participants create the Joint submission in their own IUCLID installation for better traceability later on of their Joint submission dossiers.

Nota

Each participant in the Joint submission other than the Lead must submit individually in addition to their Company identification, all confidential information, i.e. the identification of their Substance and its composition, and information on manufacture and use, including a description of the technological process, the manufacture and/or import volumes per year, the volumes for own use per year.

Click the green **Plus** button  to open the repeatable block. If more than one Joint submission has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

General information

`Joint submission name`: Insert the name assigned to the Joint submission or Consortium.

`Remarks`: If necessary introduce any additional information/comments.

`Regulatory programme`: Indicate for which regulatory programme the Joint submission is prepared. Select a value in the picklist. 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.

`Picklist options`: || EU: BPD Biocidal Products Directive 98/8/EC || EU: PPP Plant Protection Products Directive 91/414/EEC || EU: REACH Registration, Evaluation and Authorisation of Chemicals || ... ||other: ||.

Lead

Indicate the name of the Lead. Click the **Link** button  to select the Lead and establish the link. If the desired Legal entity is not present in your database, you should request it from your partners in the Joint submission. It is strongly requested **not to use the New** button to create locally the Legal entity information. It would lead to having the same Legal entities differently identified in the various IUCLID installations and would compromise data exchange.

Members

Add the name of all members of the Joint submission or consortium. Click the **Link** button  to select the member and establish the link. The same recommendations as those provided for assigning the Lead apply.

1.6. Sponsors

This section is a repeatable block section. It enables to specify different Sponsor organisations, e.g. a Competent Authority in the context of the OECD HPV Chemicals programme or a Company in the context of the US EPA HPV Challenge programme.

Click the green **Plus** button  to open the repeatable block. If more than one Sponsor has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Nota

Information on Sponsor organisations is not stored in the Legal entity inventory. Therefore it needs to be repeated in each dataset where the information is required.

- **Name**: Insert the name of the Sponsor organisation.
- **Type**: Select the type of Sponsor organisation in the picklist. Picklist options: || company || consortium || member state ||.

Contact information

Address: Enter the address of the Sponsor (e.g. Umkomaas Road 28).

Address: Use this second address line, if necessary.

Postal code: Enter the postal code (e.g. 01234).

Town: Enter the town.

Region/State: Enter the Region/State of the Sponsor organisation.

Country: Select the country in which the Sponsor organisation is located 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.

Fax: Enter the fax number of the Sponsor organisation.

E-mail: Enter the e-mail address of the Sponsor organisation.

Web site: Enter the web site of the Sponsor organisation.

Contact person

This part is a repeatable block subsection enabling to specify several contact persons. Click the green **Plus** button  to open the repeatable block. If more than one contact person has to be specified, add a new block for each one.

Organisation: Enter the name of the organisation. It may be useful if the contact person is employed by another organisation than the Sponsor organisation.

Department: Name of contact person (e.g. Scientific Department).

Title: Title of the contact person (e.g. Mr.).

First name: Of the contact person (e.g. Henri).

Last name: Of the contact person (e.g. Smith).

Phone: Of the contact person (e.g. 39 332 785241).

Mobile: Of the contact person.

Fax: Of the contact person (e.g. 39 332 785240).

E-mail: Of the contact person (e.g. henri.smith@legalentity.it).

Address: Enter the address of the contact person (e.g. Umkomaas Road 28).

Address: Use this second address line, if necessary.

Postal code: Enter the postal code (e.g. 01234).

Town : Enter the town

Region/State: Enter the Region/State of contact person.

Country: Select the country in which the contact person is located 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.

1.7. Suppliers

The term Suppliers covers Manufacturers, Importers, Formulators. This section was specifically implemented to cover certain information requirements under the EU directive for Biocidal products (98/8/EC) or to further specify Only representation conditions under REACH.

This section is a repeatable block section. It enables to specify multiple Suppliers. Click the green **Plus** button  to open the repeatable block. If more than one Supplier has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Manufacturer / importer / formulator

Name : This field may cover different types of information:

- Datasets prepared for REACH: If the Registrant specified in Section *1.1 Identification* is an Importer or an Only Representative, the name of his Manufacturer may be specified in this field.
- Datasets prepared for EU Directive for Biocidal products (98/8/EC): The active substance Manufacturer or the Manufacturer/formulator of the biocidal product may be specified in this field.

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. Follow the instructions as described in chapter D.9.2 Feature "Legal entity - New": How to create a Legal entity). The Supplier 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  and follow the instructions given in chapter D.9.3 Feature "Legal entity - Update": How to update (edit) a Legal entity). 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 .

Only representation information

Specify in the following fields - if appropriate - information on the Only representation conditions.

Official 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.

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.

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. Follow the instructions as described in chapter D.9.2 Feature "Legal entity - New": How to create a Legal entity). 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  and follow the instructions given in chapter D.9.3 Feature "Legal entity - Update": How to update (edit) a Legal entity). 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 .

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.

1.8. Recipients

A recipient can be a Downstream user, a Distributor or a Customer (e.g. in the context of Product and process orientated research and development (PPORD)) being supplied with a Substance, or a Mixture or an Article. These definitions never include consumers.

This section is a repeatable block section. It enables to specify multiple Recipients. Click the green **Plus** button  to open the repeatable block. If more than one Recipient has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Name: Indicate the name of the Recipient. d the name of the recipient. Click the **Link** button  to select the Recipient and establish the link. If the desired Recipient is not present in your database, click the **New** button. It will trigger the opening of the Legal entity creation dialogue. Follow the instructions as described in chapter D.9.2 Feature "Legal entity - New": How to create a Legal entity). The Recipient 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  and follow the instructions given in chapter D.9.3 Feature "Legal entity - Update": How to update (edit) a Legal entity). The modifications will be automatically updated by clicking the **Save** button . The **Back** button  button will lead back to section 1.8 *Recipient*. The link can be deleted by clicking the **Delete** button .

Remarks: If necessary provide any additional comments here.

1.9. Product and process oriented research and development

This section is specific to REACH. It is aimed at storing specific information on Product and Process Oriented Research and Development (PPORD). This information will then be compiled with Legal entity information, Substance identification and Substance classification to prepare a PPORD notification to be submitted to the European Chemicals Agency and be exempted from the general obligation to register.

This section is a repeatable block section. It enables to specify multiple PPORD programmes. Click the green **Plus** button  to open the repeatable block. If more than one PPORD programme has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Name: Insert the name of the PPORD programme.

Medicinal product for human veterinary use: Select the checkbox if the substance is used exclusively in the development of medicinal products for human or veterinary use. This information is mostly used for requesting an extension of the five-year initial exemption period.

Substance not placed on the market: Select the checkbox if the substance is not placed in the market. This information is mostly used for requesting an extension of the five-year initial exemption period.

Estimated quantity: Insert the overall manufacture and/or imports in tonnes per manufacturer or importer per year (Under REACH, per year means in the calendar year of the notification).

Remarks: If necessary provide any additional comments here.

Document: Add any useful documentation or justification. 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.

2. [2] Classification and Labelling

The classification and labelling is divided into two subsections:

1. Subsection *2.1 GHS* contains the classification and labelling information according to the Globally Harmonized System of classification and labelling of chemicals (GHS).
1. Subsection *2.2 DSD – DPD* contains the classification and labelling information according to the European directive 67/548/EEC for classification and labelling of substances and according to the European directive 1999/45/EC for classification and labelling of preparations.

The European directive 67/548/EEC for classification and labelling of substances is also known as the Dangerous Substances Directive (DSD). The European directive 1999/45/EC for classification and labelling of preparations is also known as the Dangerous Preparations Directive (DPD). The implementation of this section is done in a generic way, i.e. the same section is used both for preparations (mixtures) and substances. Therefore the name given to the section is also generic and includes both directives.

Attenzione

Mixtures (also known as Preparations) and their classification and labelling information should be entered in the dataset specially dedicated to Mixtures. See chapter D.7.2 Creating and populating a Mixture dataset for more information on mixtures and their implementation in IUCLID.

A Substance may have multiple classification and labelling records, for instance in the case the substance contains an impurity having specific hazard properties leading to a specific impact on the classification. A Mixture can also have multiple classification and labelling records for instance in the case of different compositions.

IUCLID offers the possibility to store these multiple records whatever the system used, i.e. GHS or DSD – DPD, by using the repeatable block functionality (see chapter D.4.5.5.3 Repeatable blocks of fields).

2.1. GHS

GHS is a repeatable block section. Click the green **Plus** button  to open the repeatable block. The data entry screen appears and an empty block is now ready to be filled in. Add a new block for each individual classification and labelling you may have.

Set the confidentiality/regulatory purpose information for each individual record created. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

General information

Name: When a Substance or a Mixture has more than one classification and labelling record it is recommended to specify a name for each individual record so that they can be easily identified (e.g. "classification with more/equal 0.1% of substance C" and "classification with less than 0.1% of substance C").

Not classified: Check this box if your Substance or Mixture is not classified.

Implementation: The GHS implementation can be different depending on certain regions (e.g. EU, Japan, Australia). Specify the Implementation by selecting from the drop-down list. If none of the pre-defined items applies, select **other**:. A text field is then activated next to the list field in which you can enter any freetext. If you wish to record a GHS for another region, add a new block.

Remarks: If necessary provide any additional comments here.

Remaining fields: To define the classification and labelling of your Substance or Mixture as required in the GHS, fill in the fields included in the following sections.

Classification

Physical hazards

Health hazards

Germ cell mutagenicity (repeatable block subsection)

Carcinogenicity

Specific target organ toxicity - single (repeatable block subsection)

Specific target organ toxicity - repeated (repeatable block subsection)

Environmental hazards

Additional hazard classes

Labelling

Hazard statements (repeatable block subsection)

Additional precautionary statements (repeatable block subsection)

Additional labelling requirements (repeatable block subsection)

Specific concentration limits (repeatable block subsection)

Hazard categories (repeatable block subsections)

Notes

2.2. DSD-DPD

The **Classification and Labelling under European directives 67/548/EEC (DSD) and 1999/45/EC (DPD)** is a repeatable block section.

Click the green **Plus** button  to open the repeatable block. The data entry screen appears and an empty block is now ready to be filled in. Add a new block for each individual classification and labelling you may have.

Set the confidentiality/regulatory purpose information for each individual record created. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

General information

Name: When a Substance or a Mixture has more than one classification and labelling record it is recommended to specify a name for each individual record so that they can be easily identified (e.g. "classification with more than 0.1% of substance C" and "classification with less than 0.1% of substance C").

Not classified: Select this checkbox if your Substance or Mixture is not classified.

Status: Select from the drop-down list to indicate whether the classification record was based on the Annex I of Council Directive 67/548/EEC or on self classification following the criteria specified in Annex VI of Council Directive 67/548/EEC. 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.

Index number: Indicate the index number if the substance is classified in Annex I of 67/548/EEC.

ATP inserted: Indicate the first insertion in the Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC.

ATP last update: Indicate the last update to the Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC.

Remarks: If necessary provide any additional comments here.

Remaining fields: To define the classification and labelling of your Substance or Mixture required by DSD-DPD, fill in the fields included in the following sections.

Nota

If the classification and labelling is defined for a REACH dossier, according to Annex VI, of the REACH regulation, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).

Classification

Indicate the classification or the reason for no classification selecting the corresponding checkbox(es) (or entries) in the related drop-down list boxes or drop-down combo-boxes:

Explosiveness

Oxidising properties

Flammability

Thermal stability

Acute toxicity

Acute toxicity - irreversible damage after single exposure

Repeated dose toxicity

Irritation / Corrosion

Sensitisation

Carcinogenicity

Mutagenicity - Genetic Toxicity

Toxicity to reproduction - fertility

Toxicity to reproduction - development

Toxicity to reproduction - breastfed babies

Environment

Labelling

Indication of danger (repeatable block subsection)

Risk phrases (repeatable block subsection)

Safety phrases (repeatable block subsection)

Specific concentration limits (repeatable block subsection)

Indication of danger (symbols) (repeatable block subsection)

Notes (repeatable block subsection)

3. [3] Manufacture, Use and Exposure

This section covers:

- Description of the technological process(es) used in production.
- Volume information for production, import, own use of the substance and volumes used as intermediates.
- Location of the production and own use sites.
- Availability of the substance in the supply chain.
- Uses and exposure scenarios, exposure estimates.
- Information on waste, biocide product types.
- Specific information for application for authorisation of certain uses of the substance.

3.1. Technological process

This section is a repeatable block section, which offers the possibility to provide several descriptions of the technological process used in the manufacture of the substance or production of articles, as appropriate.

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.

Set the confidentiality and regulatory purpose flags. The flags are related to a single block, i.e. a single process description. They should be set for every newly created block see chapter D.4.5.7 Flags used for filtering data.

Methods of manufacture: Describe the technological process used for the manufacture of the substance or the production of the articles in which the substance is being used. It might include specification of the type of reaction (e.g. fluid-bed reaction) the system in which the substance is processed (open/closed, continuous/batchwise), duration and frequency of processing, maximum capacity per time-unit, pressure and temperature during processing, solvents used, processing efficiency).

If no information is available, the justification may be entered in this field.

3.2. Estimated quantity

Indicate here the estimated production/imports quantity in tonnes per calendar year or multi-yearly average.

Tabella E.3. Estimated quantity

Year	Specify the year to which the estimated quantity is related.
Tonnage	Insert the estimated volume of the production/use/import chemical in tonnes.
Own use	Insert the indication of the tonnage used for your own use.
Intermediate (On-site)	Insert the indication of the tonnage used as intermediate (on-site).
Intermediate (Transported)	Insert the indication of the tonnage used as intermediate (transported).

Remarks: If necessary provide any additional comments here.

Nota

For registration of substance under REACH regulation (EC 1907/2006) the quantities have to be considered in the calendar year of the registration.

3.3. Sites

This section is a repeatable block section, which offers the possibility to list all sites where the Substance or Mixture is produced and/or used. This is done by creating for each site a link with the relevant information stored in the Legal entity site inventory. For more information on Legal entity site, see chapter D.10 Legal entity sites (create and update Legal entity sites).

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.

Attenzione

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. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

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  and follow the instructions given in chapter D.10.2 Feature "Legal entity sites - New": How to create a Legal entity site. 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 .

Attenzione

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.

`Production site`: Select the checkbox to specify if the Substance or Mixture is produced in this Site.

`Use site`: Select the checkbox to specify if Substance or Mixture is used in this Site.

Nota

In case of a Distributor only, no checkbox should be selected.

3.4. Form in the supply chain

Information on the form (Substance, Mixture or Article) and on the physical state under which the substance is made available in the supply chain should be entered here.

Nota

This section concerns only Substances and therefore is not available in a Mixture dataset.

This section is a repeatable section. Click the green **Plus** button  to open a new repeatable block. An empty block is now ready to be filled in. Add a new repeatable block if it is necessary to specify different forms in which the Substance is present in the supply chain.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Available as substance

`Available as substance`: Select the checkbox if the Substance is available as such.

Substance in mixture

Substance in mixture: Select the checkbox if the Substance is placed on the market as a Mixture (i.e. preparation).

Click the green **Plus** button  to open the second level repeatable block to enter further information on the Mixture. An empty block is now ready to be filled in.

Trade name of mixture: Insert the trade name of the mixture (i.e. preparation).

Type of mixture: Enter a description of the Mixture (e.g. granulate, paste, solution etc.).

Typical concentration: Insert the maximum content and/or the range of the concentration of the Substance in the mixture, as made available to downstream users. If the Substance is part of more than one Mixture, add as many repeatable blocks as necessary.

Substance in article

Substance in article: Select the checkbox if the substance is part of an article.

Nota

The definition of an article may differ depending on the regulatory programme. Under the REACH regulation, the article is "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition." Click the green **Plus** button  to open the second level repeatable block to enter further information on the article. An empty block is now ready to be filled in. If the Substance is part of more than one Article, add as many repeatable blocks as necessary.

Description of article: Specify information on the article, such as:

- its function (the purpose of its use).
- its shape (description of the object from a dimensional point of view - depth, width and height).
- its surface (outermost layer of the object).
- its design (arrangement of the elements of design to best accomplish a particular purpose).
- all other possible article identifiers.

Nota

In the context of the REACH regulation, further information is available in the "Guidance on fulfilling the Requirements for articles". For more information see chapter A.4.1 Other technical manuals.

Amount

Tonnage: Insert the maximum content of the concentration of the Substance in the article in tonnes.

Remarks: If necessary provide any additional comments here.

3.5. Identified uses and exposure scenarios

This section enables to provide:

- Information on exposure: The main use category, the significant route(s) of exposure and the pattern of exposure can be specified.

Nota

In the REACH regulation (section 6 of Annex VI), this information is required for substances registered in quantities between 1 and 10 tonnes per year per Manufacturer or Importer. For substances above 10 tonnes, it is not sufficient and exposure scenarios must be prepared.

- Information on the identified uses: This part offers a multi-level structured system enabling to categorise the type of use of the Substance by using standard descriptors instead of free text information. The combination of the four levels of descriptors represents the brief description of use as required in the REACH regulation in section 3.5 of Annex VI and can also be considered as the short title of the exposure scenario that needs to be prepared for substances above 10 tonnes.

Attenzione

This short title for an exposure scenario and/or the brief general description of a use cannot replace the exposure scenario itself because the exposure scenario provides, where required, a more detailed and quantifiable description of the conditions of use ensuring adequate control of risk. Therefore the short title and/or the brief general description of a use, as provided in IUCLID should rather be seen as a way to describe a use in general in the registration dossier as required in Annex VI of REACH. For more information on exposure scenario and standard descriptors, see "Technical Guidance Document on preparing the Chemical Safety Report (CSR)". For more information see chapter A.4.1 Other technical manuals.

Uses and exposure

Overall use and exposure

Enter the information on exposure using the overall use and exposure schema.

Main use category

Select the corresponding main use category per manufacturer or importer. If necessary, more than one checkbox can be selected.

- Industrial use
- Professional use
- Consumer use

Specification for industrial and professional use

Specify how the substance is used during its life-cycle. If necessary, more than one checkbox can be selected.

- Used in closed system
- Use resulting in inclusion into or onto matrix
- Non-dispersive use
- Dispersive use

Significant routes of exposure

Human exposure

Specify the route(s) of exposure. If necessary, more than one checkbox can be selected.

- Oral
- Dermal
- By inhalation

Environmental exposure

Specify the environment compartment. If necessary, more than one checkbox can be selected.

- Water
- Air
- Solid waste

- Soil

Pattern of exposure

Specify the pattern of exposure. If necessary, more than one checkbox can be selected.

- Accidental/infrequent
- Occasional
- Continuous/frequent

Identified uses and exposure scenarios

Identified use

The Identified use is structured in a hierarchical way aiming at facilitating the indication of "brief general description of use(s)". There are several levels of descriptors:

- The first level concerns the Application technique or process. No standard descriptors have been developed yet, therefore this field is a free text field. Refer to further progress on this aspect in the context of the "Technical Guidance Document on preparing the Chemical Safety Report (CSR)" to use appropriate terminology. For more information see chapter A.4.1 Other technical manuals.
- The second level concerns the use category. Under each Application technique one or more Use category for each type of product (substance as such or in mixture) can be specified for defining further its technical function (e.g. dispersant, polishes and wax blends, etc.). The standard descriptors are based on the UC 55 picklist of the current TGD, the UCN codes applied in the Nordic product registering systems and the ECETOC TRA product category approach. For more detail, refer to the "Technical Guidance Document on preparing the Chemical Safety Report (CSR)". For more information see chapter A.4.1 Other technical manuals.
- The third level concerns the Industry category. Under each Use category, one or more Industry category (i.e. the sector where the Substance or Mixture is applied (e.g. manufacture of textiles) can be specified. The standard descriptors are based on a selection of the most relevant NACE codes. In case of Articles, it is possible to further categorise at that level the type of Article, (e.g. plastic products: toys / rubber products: tyres, etc).

Nota

In case of intermediates, i.e. substances that are used only for transformation into another substance, the exclusive use of industry process descriptors might not be appropriate. As the system of standard-descriptors can be expanded with new descriptors, you can always refer to the updated list and write in the freetext field the appropriate.

Click the green **Plus** button  to open the repeatable block to enter information on each identified use. An empty block is now ready to be filled in.

Brief description: Enter a description of the identified use of your substance.

Attenzione

This field is not sufficient for REACH registrations. It is useful for quickly identifying the use as the information entered in this field appears in the title bar when the repeatable block is in condensed format (by using the **Fold** button ). Nevertheless, the hierarchical system of standard descriptors has to be used to properly describe the identified use as required in REACH.

Application technique level

Click the green **Plus** button  to open the second level repeatable block and enter information on the Application technique/activity. An empty block is now ready to be filled in.

Application technique/Activity: Refer to guidance provided in the "Technical Guidance Document on preparing the Chemical Safety Report (CSR)" to enter the appropriate terminology to specify the Application technique or process in this free text field. For more information on guidance manuals see chapter A.4.1 Other technical manuals.

Use category level

Click the green **Plus** button  to open the third level repeatable block and enter information on the Use category. An empty block is now ready to be filled in. If more than one Use category for the same Application technique has to be specified, add a new block for each one.

Use category: Select a Use category descriptor in the picklist to indicate the technical function/purpose of the Substance or the Mixture (e.g. coatings, lubricants, adhesives, inks, textile finishing chemicals, alloys) in which the substance is applied for end-use.

Nota

The picklist is divided in two different categories of uses and each item in the list is made of two parts:

1. Technical function of substance: this category describes the function of the substance itself (e.g. || adhesion promoter || technical function of substance).
2. Substances and Preparations for final use: this category describes the type of final product (e.g. || adhesives, sealants || substances and preparations for final use).

If none of the pre-defined descriptor applies, select **other:**. A text field is then activated next to the list field in which you can enter any free text..

Suggerimento

It is preferable to define the `|| other: ||` option using the terminology employed in UCN (<http://www.arbejdstilsynet.dk/sw12578.asp#afsa>) or TARIC system. If you need to include an innovative descriptor, use the freetext to describe it.

`Available as substance:` For each entered Use category, select this checkbox to indicate whether the use refers to the substance as such.

`Available in mixture:` For each entered Use category, select this checkbox to indicate whether the use refers to the substance in a mixture.

Industry category level

Click the green **Plus** button  to open the fourth level repeatable block and enter information on the Industry category. An empty block is now ready to be filled in. If more than one Industry category for the same Use category has to be specified, add a new block for each one.

`Industry category:` Select an Industry category descriptor in the picklist to indicate in which sectors of economy (including private households, public domain) the Substance or Article is used.

Nota

As mentioned above, this picklist is based on the NACE system nomenclature (statistical classification of economic sectors. See http://ec.europa.eu/eurostat/ramon/index.cfm?TargetUrl=DSP_PUB_WELC [http://ec.europa.eu/eurostat/ramon/index.cfm?TargetUrl=DSP_PUB_WELC]), Each Industry category picklist descriptor has three levels of information. See the structure of the following picklist item: `|| C19 - manufacturing: manufacture of coke and refined petroleum products:|`

- `C19` : NACE code 2007.
- `manufacturing` : fist hierarchy level of NACE 2007.
- `manufacture of coke and refined petroleum products:` detailed level of the manufacture of chemicals (or chemical product).

If none of the pre-defined descriptor applies, select **other:**. A text field is then activated next to the list field in which you can enter any free text.

Suggerimento

It is preferable to define the `||other: ||` option using the terminology employed in the NACE system. If you need to include an innovative descriptor, use the freetext to describe it.

Type of article: Select one or more values in the picklist to further describe the type of Articles if appropriate.

Nota

This picklist is linked to the combination of Application technique / Use category / Industry category provided upfront. If the use described by using those picklists results in the incorporation of the Substance in an Article, this should be indicated by using the Article picklist. The picklist covers Article types from which the substance can be intentionally released and Article types from which the substance will not be released or released unintentionally.

No intended release descriptors are based on the product categories used in the Targeted Risk Assessment tool developed by ECETOC (Targeted Risk Assessment, Technical Report 93, December 2004). Intended release descriptors are based on an indicative list of examples discussed in the framework of the TGD for requirements for substances in articles.

Suggerimento

Each Article type picklist descriptor has several levels of information: the TRA category code (when applicable), the descriptor itself and the information of no intended release and intended release. See the structure of the following picklist item: || C06 - Fabrics, textiles and apparel: bedding and clothing (no intended release):

- C06 : indicates the TRA category (ECETOC's Targeted Risk Assessment Method).
- Fabrics, textiles and apparel: bedding and clothing: Article type descriptor.
- (no intended release): the substance is not released or unintentionally released.

If none of the pre-defined descriptor applies, select **other**:. A text field is then activated next to the list field in which you can enter any free text.

Suggerimento

It is preferable to define the || **other**: || option using the terminology employed in the NACE system or the TARIC system. If you need to include an innovative descriptor, use the freetext to describe it.

Exposure scenario

A short title of the exposure scenario can be provided and/or it is possible to attach the exposure scenario document.

Nota

For REACH registration dossiers, the exposure scenario has to be included in any case (for substances above 10 tonnes) in the Chemical Safety Report. This IUCLID section offers a repository to attach the exposure scenario related to each identified use for better traceability of your information.

Click the green **Plus** button  to open the repeatable block and enter information on the exposure scenario. An empty block is now ready to be filled in. If more than one exposure scenario has to be specified, add a new block for each one.

Description: Enter the short title of the exposure scenario. It can be the combination Application technique / Use category / Industry category (Article types if appropriate).

Document: Attach the exposure scenario by clicking the **Attachment** button  and 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.

3.6. Uses advised against

This section enables to provide information on use(s) advised against as specified in the REACH regulation (section 3.7 of Annex VI).

The hierarchical structure of this section is similar to the structure of the Part Identified use in the previous section. Moreover the standard descriptor system is strictly the same as for the Identified uses. Please refer to all indications described in chapter E.3.5. Identified uses and exposure scenarios to fill-in the required information.

3.7. Waste from production and use

This section is a repeatable block section enabling to provide information on waste quantities and composition of the waste resulting from the production and identified use(s) as specified in the REACH regulation (section 3.6 of Annex VI). Click the green **Plus** button  to open the repeatable block and enter information on the waste. An empty block is now ready to be filled in. If more than one type of waste needs to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Estimated quantities: Enter the estimated quantities of waste resulting from the production as well as the identified use(s).

Composition: Enter a description of the composition of the waste resulting from the production as well as the identified use(s).

Remarks: If necessary provide any additional comment here. (i.e. justify why the information is not available although it is requested by the regulatory programme).

3.8. Exposure estimates

This section enables to provide information on the exposure estimates related to production and use.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Exposure related to production

Working environment: The most relevant moments of exposure related to production should be described (for instance during filling, weighing, cleaning activities, sampling for quality and process control, in case of irregularities, etc...). Also, the likely pattern of control (if requested by the legislation) could be provided here.

Indirect exposure to humans: Provide the information of the activities of workers related to the processes and the duration and frequency of their exposure to the substance (if available, enter details concerning the number of workers involved, level, route and duration and frequency of exposure, could be provided for both during the working period, and averaged over a longer period during working life). Also, the likely pattern of control (if requested by the legislation) could be provided here.

Environment: Describe the duration and frequency of emissions, of the substance to the different environmental compartments, and sewage treatment systems. The dilution in the receiving environmental compartment should be provided. Also, the likely pattern of control (if requested by the legislation) could be provided here.

Exposure related to use

Working environment: The most relevant moments of exposure related to the use should be described, for instance, during filling, weighing, cleaning activities, sampling for quality and process control, in case of irregularities, etc. Also, the likely pattern of control should be provided.

Consumers: The most relevant moments of exposure related to the final consumers should be described. Also, the likely pattern of control (if requested by the legislation) could be provided here.

Indirect exposure to humans: The most relevant moments of indirect exposure related to humans of the substance (i.e. along the supply chain) should be described. Also, the likely pattern of control (if requested by the legislation) could be provided here.

Environment: Describe the duration and frequency of emissions, of the substance to the different environmental compartments, and sewage treatment systems derived from the use of the substance. Also, the likely pattern of control (if requested by the legislation) could be provided here.

3.9. Biocidal information substance

This section enables to provide specific biocidal product information, in particular the product type. It is intended to be used for preparing of a biocide dossier submission for inclusion in Annex I of Directive 98/8/EC or for Authorisation of a Biocidal product according to Directive 98/8/EC.

Click the green **Plus** button  to open the repeatable block and enter the biocidal information. An empty block is now ready to be filled in. If more than one type of product type needs to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

User

`industrial`: Select the checkbox in case of the Substance/product is used by industrial users.

`other_professional`: Select the checkbox in case of the Substance/product is used by professional users other than industrial users (e.g. pest controller, carpenter, cleaner, etc.).

`general_public`: Select the checkbox in case of the Substance/product is used by the general public.

`Product_type`: Select one of the 23 product types as defined by Directive 98/8/EC.

`Remarks`: If necessary, provide any additional comments here.

Volume information

Provide the information on volume of the biocidal product, adding new lines for each calendar year and tonnage. For each entry add a new row in the table by clicking the green **Plus** button .

Tabella E.4. Volume information

Year	Specify the year to which the tonnage is related.
Tonnage	Insert the estimated tonnage of the production/use/import of the biocidal product.
Remarks	If necessary, provide any additional comments here.

3.10. Application for authorisation of uses

This section is specific to REACH. It is aimed at storing specific information to apply for an authorisation of use in case the Substance is listed in Annex XIV of the regulation ("List of substances subject to authorisation"). This information will then be compiled with Legal entity information, Substance identification and the Chemical Safety Report - if appropriate - to prepare an application for authorisation for one or several uses.

This section is a repeatable block section. It enables to specify multiple applications for authorisation. Click the green **Plus** button  to open the repeatable block. If more than one application for authorisation has to be specified, add a new block for each one.

Set the confidentiality flag and regulatory purpose. For a description of these flags see chapter D.4.5.7 Flags used for filtering data.

Request for authorisation

This subsection is repeatable. It enables to regroup several uses of the Substance in the same application provided that all subsequent information (i.e. analysis of the alternatives, socio-economic analysis, substitution plan, etc.) is valid for all the regrouped uses. Click the green **Plus** button  to open the repeatable block and describe a use for which the application is intended. An empty block is now ready to be filled in. If more than one use needs to be specified, add a new block for each one.

Use concerned by the request: Indicate the use of the substance. If appropriate, use the combination Application technique / Use category / Industry category (as described in chapter E.3.5 Identified uses and exposure scenarios) to better categorise the use.

Analysis of the alternatives

Describe the analysis of the alternatives considering their risks and the technical and economic feasibility of substitution. The analysis of the alternative should include all appropriate information about any relevant research and development activities made by you.

Socio-economic analysis

The socio-economic analysis (SEA) shall be provided following the format and the "Technical Guidance Document on carrying out a Socio-Economic Analysis or input for one" made by the European Chemical Agency (www.echa.eu [<http://www.echa.eu/>]) on preparation of SEAs.

Remarks: If necessary provide any additional comment here.

Document: Add the SEA documentation by clicking 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.

Substitution plan

If suitable alternatives are available, attach the substitution plan foreseen, including a timetable for your proposed actions.

Remarks: If necessary provide any additional comment here.

Document: Attach the substitution plan document by clicking 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.

Justification for not considering risks to human health and environment

Remarks: Enter the justification for not considering risks to human health and the environment arising either from emissions of a substance or discharges of a substance.

Reference to other application of previous authorisations

If you have the permission from a previous applicant who applies for authorisation of the same specific use of your substance, you can refer to the appropriate parts of the previous application submitted. Furthermore if you have the permission from the holder of a previous granted authorisation, you may refer to the appropriate parts of the previous application submitted.

Click green **Plus** button  to open the repeatable block and describe the reference to previous authorisations or other applications for which you have a written permission. An empty block is now ready to be filled in. If more than one reference needs to be specified, add a new block for each one.

Written permission: Select the checkbox only if you have a written permission from the previous applicant.

Remarks: If necessary provide any additional comment on the previous authorisation.

4. [4] Physical and chemical properties

4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

4.2. [4.1] Appearance/physical state/colour

4.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.5. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.2.1.3. 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.

4.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.2.1.6. 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. US EPA in addition to OECD guideline).

Tabella E.6. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.2.1.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.2.1.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.2.1.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.2.1.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.7. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.2.1.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.2.1.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.2.1.13. 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.

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.

4.2.1.14. Physical state at 20°C and 1013 hPa

Indicate physical state of the substance at 20°C and 1013 hPa, i.e. gaseous, liquid or solid. If other environmental conditions apply, specify them in the supplementary remarks field.

Note: As appropriate, create separate records if (slightly) different appearance, physical state and colour need to be reported, e.g. from another manufacturer . Include a remark on this in the supplementary remarks field.

Note: The various fields under "Administrative data", "Data source" and "Materials and methods" can be disregarded if only information on appearance etc. is provided without reference to any studies conducted. Where relevant, also provide information on test guidelines used etc.

4.2.1.15. Form

Select the physical form of the substance from picklist, e.g. powder, crystalline, compact, viscous, etc. If the substance can have more than one form, copy this field as appropriate.

4.2.1.16. Colour

Describe colour of the substance at 20°C and 1013 hPa. If other environmental conditions apply, specify them.

4.2.1.17. Odour

Select the odour of the substance from picklist, e.g. biting, pungent, etc

4.2.1.18. Substance type

Select as appropriate or use "other:" to describe substance type if not available from picklist.

4.2.1.19. 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.

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.

4.2.1.20. 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.

Tabella E.8. Field Descriptions

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.
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.

4.2.1.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.2.1.22. Conclusions

Enter any conclusions if applicable.

4.2.1.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.2.1.24. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.3. [4.2] Melting point/freezing point

4.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.3.1.2. Melting / freezing point at 101 325 Pa in kelvin (K)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.9. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.3.2.3. 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.

4.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.10. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.3.2.7. 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.

4.3.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.3.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.3.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.3.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.11. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.3.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.3.2.14. 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.

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.

4.3.2.15. Melting / freezing point

Enter mean value of melting/freezing point or range if reported so, together with data on atmospheric pressure, decomposition and sublimation as applicable. For comparison reason, temperature data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. Likewise, pressure data should be given in hPa. By copying this block of fields both the the original and converted value(s) can be entered.

Tabella E.12. Field Descriptions

Melting / freezing point (Melt./Freez. pt.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Atm. pressure	Enter a numeric value or a range of numeric values according to following conventions:

Specific Guidance on Content of IUCLID Sections

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
(no label)	Select from drop-down list.
Decomposition	Indicate whether decomposition occurs. Any remarks can be entered in the supplementary remarks field.
Decomp. temp.	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
(no label)	Select from drop-down list.
Sublimation	Indicate whether sublimation occurs. Any remarks can be entered in the supplementary remarks field.
Subl. temp.	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
(no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded value as appropriate, e.g. on estimate of accuracy (e.g. "approx. maximum accuracy of melting pt. +/-0.3 °C").

4.3.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.3.2.17. 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.

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.

4.3.2.18. 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.

Tabella E.13. Field Descriptions

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.
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.

4.3.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.3.2.20. Conclusions

Enter any conclusions if applicable.

4.3.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.3.2.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.4. [4.3] Boiling point

4.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa

- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.4.1.2. Boiling point at 101 325 Pa in kelvin (K)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.4.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.4.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.4.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.4.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.14. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.

Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.
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4.4.2.3. 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.

4.4.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.4.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.4.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.15. Field Descriptions

Qualifier	Select appropriate qualifier, i.e.
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	<ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.4.2.7. 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.

4.4.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.4.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.4.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.4.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.16. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
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Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.
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4.4.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available

- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.4.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.4.2.14. 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.

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.

4.4.2.15. Boiling point

Enter mean value of boiling point or range if reported so, together with data on atmospheric pressure, decomposition and sublimation as applicable. For comparison reason, temperature data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. Likewise, pressure data should be given in hPa. By copying this block of fields both the the original and converted value(s) can be entered.

Tabella E.17. Field Descriptions

Boiling point (Boiling pt.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Atm. pressure	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
(no label)	Select from drop-down list.
Decomposition	Indicate whether decomposition occurs. Any remarks can be entered in the supplementary remarks field.
Decomp. temp.	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
(no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded value as appropriate, e.g. on estimate of accuracy (e.g. "approx. maximum accuracy of boiling pt. +/-0.3 °C").

4.4.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.4.2.17. 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.

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.

4.4.2.18. 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.

Tabella E.18. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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4.4.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.4.2.20. Conclusions

Enter any conclusions if applicable.

4.4.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.4.2.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.5. [4.4] Density

4.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.5.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.5.1.2. Density in g/L (= kg/m³) at 20°C

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.5.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.5.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.5.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.5.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.19. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.5.2.3. 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.

4.5.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.5.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.5.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.20. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.5.2.7. 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.

4.5.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.5.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.5.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.5.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.21. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.5.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.5.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.5.2.14. 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.

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.

4.5.2.15. Density

Select type of density, e.g. bulk density (in kg/m³; for solids only), density in g/cm³ or dimensionless relative density (related to water at 4 °C) and enter mean value or range if reported so. For relative density, leave subfield "Unit" empty. If another water temperature than 4 °C applies or if another reference material was used, select "other:" in subfield "Unit" and specify accordingly.

Also provide the temperature at which the density of the test material was determined. For comparison reason, the data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. By copying this block of fields both the the original and converted value(s) can be entered.

Tabella E.22. Field Descriptions

Type	Select from drop-down list.
Density	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

Temp.	Enter numeric value.
(no label)	Select from drop-down list.

4.5.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.5.2.17. 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.

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.

4.5.2.18. 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.

Tabella E.23. Field Descriptions

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.
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.

4.5.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.5.2.20. Conclusions

Enter any conclusions if applicable.

4.5.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.5.2.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.6. [4.5] Particle size distribution (Granulometry)

4.6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.6.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.6.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.6.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.6.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.6.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.24. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.6.2.3. 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.

4.6.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.6.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.6.2.6. Type of distribution

Indicate whether the type of distribution is volumetric or counted.

4.6.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.25. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.6.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.6.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.6.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.6.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.26. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.6.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.6.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.6.2.14. 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.

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.

4.6.2.15. Mass median diameter

Specify the mass median diameter.

Tabella E.27. Field Descriptions

Mass median diameter (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

4.6.2.16. Particle size

Specify the percentile and the size in μm or mm determined. Copy this block of fields for indicating other percentiles.

Give any further relevant information in the field "Any other information on results incl. tables" as appropriate.

Tabella E.28. Field Descriptions

Percentile	Indicate the percentile at which the particle size was determined.
Mean value of particle size (Mean)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of particle size (no label)	Select from drop-down list.
Standard deviation (St. dev.)	Give the mean numeric value of size measured at the given percentile.

4.6.2.17. Particle size distribution at different passages

For each passage (normally three), provide the size range in µm or mm and its distribution in % or ppm.

Give any further relevant information in the field "Any other information on results incl. tables" as appropriate.

Tabella E.29. Field Descriptions

Passage No. (No.)	Select a consecutive passage number from drop-down list.
Size	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of size (no label)	Select from drop-down list.

Distribution	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of distribution (no label)	Select from drop-down list.

4.6.2.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.6.2.19. 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.

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.

4.6.2.20. 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.

Tabella E.30. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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4.6.2.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.6.2.22. Conclusions

Enter any conclusions if applicable.

4.6.2.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.6.2.24. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.7. [4.6] Vapour pressure

4.7.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.7.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)
- Genetic toxicity:
In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.7.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.7.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.7.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.7.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.7.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.31. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	

	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.7.2.3. 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.

4.7.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.7.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.7.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.32. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.7.2.7. 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.

4.7.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.7.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.7.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.7.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.33. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.7.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.7.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.7.2.14. 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.

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.

4.7.2.15. Vapour pressure

Enter vapour pressure and the corresponding temperature in the respective subfields. For comparison reason, the data should be recorded in hPa. If reported in other units, it is recommended to convert to hPa.

Copy this block of fields for each temperature at which a vapour pressure was determined or for indicating estimates of vapour pressure at 20 or 25°C determined in pre-tests as may be required according to specific test guidelines. If so, include a note ("estimate") in subfield "Remarks".

Give any further relevant information in the field "Any other information on results incl. tables" as appropriate. For a robust study summary, attach a log p vs. 1/T curve.

Tabella E.34. Field Descriptions

Qualifier (no label)	Leave this subfield empty if the vapour pressure is equal to the specified value. Otherwise select appropriate qualifier from drop-down list, i.e. <, <=, >, >= or ca.
Vapour pressure (no label)	Enter numeric value.

Unit (no label)	Select from drop-down list.
Qualifier (at)	Leave this subfield empty if the temperature is equal to the specified value. Otherwise select appropriate qualifier from drop-down list, i.e. <, <=, >, >= or ca.
Temperature (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded value as appropriate.

4.7.2.16. Transition / decomposition

Indicate whether any transition (change of state, decomposition) was observed. If yes, indicate the temperature at which it occurs at atmospheric pressure and the vapour pressure at 10 and 20 °C above this temperature (unless the transition is from solid to gas).

Tabella E.35. Field Descriptions

Transition / decomposition	Indicate whether any transition (change of state, decomposition) was observed. If yes, state the nature of transition in the supplementary remarks field.
Transition temperature (at)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Vapour pressure at 10°C above transition temperature	Indicate whether any transition (change of state, decomposition) was observed. If yes, state the nature of transition in the supplementary remarks field of field "Transition / Decomposition". In the respective subfields, indicate the temperature at which it occurs at atmospheric pressure and the vapour pressure at 10 and 20 °C above this temperature (unless the transition is from solid to gas).
Unit (no label)	Select from drop-down list.
Vapour pressure at 20°C above transition temperature	Enter numeric value.

Unit (no label)	Select from drop-down list.
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4.7.2.17. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.7.2.18. 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.

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.

4.7.2.19. 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.

Tabella E.36. Field Descriptions

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.
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.

4.7.2.20. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.7.2.21. Conclusions

Enter any conclusions if applicable.

4.7.2.22. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.7.2.23. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.8. [4.7] Partition coefficient

4.8.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.8.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.8.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.8.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.8.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.8.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.8.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.37. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.8.2.3. 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.

4.8.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.8.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.8.2.6. Partition coefficient type

Indicate the type of partition coefficient, normally "octanol-water". Select "other:" and specify as appropriate. Note: Data on the Henry's law constant (air - water partition) should be entered in the respective chapter; data on Kd values (e.g., partition / distribution coefficients for soil or sediment) should be recorded in chapters "Adsorption / desorption" or "Other distribution data".

4.8.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.38. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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4.8.2.8. 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.

4.8.2.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.8.2.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.8.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.8.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.39. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.8.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.8.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

4.8.2.15. Analytical method

Select / repeat field as appropriate. If not available from picklist, select "other" and specify.

In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.

4.8.2.16. Details on methods

Provide details on the methods. If an estimation method was used (to be indicated in field "Test result type") state the equation(s) applied to calculate the value. For experimental studies, use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.8.2.17. 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.

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.

4.8.2.18. Partition coefficient

Enter overall mean partition coefficient or lower and upper value in case of range determined at the temperature and pH conditions indicated in the respective subfields. Copy this block of fields for each temperature and pH conditions at which the partition coefficient was determined or for indicating both Pow and log Pow values.

Tabella E.40. Field Descriptions

Type	Indicate if Pow or log Pow is given.
Partition coefficient	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p>

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
pH	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

4.8.2.19. Details on results

Give any further relevant information. As appropriate include table(s) with raw data in the rich text field "Any other information on results incl. tables". 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 requested by the regulatory programme, also attach a chart of relation and fitted regression equation (which includes a correlation coefficient) in field "Attached background material".

4.8.2.20. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.8.2.21. 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.

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.

4.8.2.22. 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.

Tabella E.41. Field Descriptions

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.
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.

4.8.2.23. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.8.2.24. Conclusions

Enter any conclusions if applicable.

4.8.2.25. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.8.2.26. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.9. [4.8] Water solubility

4.9.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.9.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.9.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.9.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.9.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.9.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.9.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.42. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.9.2.3. 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.

4.9.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.9.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.9.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.43. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.9.2.7. 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.

4.9.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.9.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.9.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.9.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.44. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.9.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.9.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.9.2.14. Details on methods

Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used. If the test substance appears "insoluble" in water, provide the detection limit of the analytical method. Also provide the purity of water used.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) applied to calculate the water solubility.

4.9.2.15. 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.

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.

4.9.2.16. Water solubility

Enter mean water solubility or range if reported so and indicate the temperature and pH conditions in the respective subfields. If necessary, copy this block of fields for each temperature and pH conditions at which the water solubility was determined.

If the pH value was measured with another test substance concentration than the given water solubility concentration, specify the concentration with unit in field "Details on remarks".

Tabella E.45. Field Descriptions

Water solubility (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>
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	(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").
Unit of water solubility (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
pH value (pH)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

4.9.2.17. Details on results

Give any further relevant information. As appropriate include table(s) with raw data in the rich text field "Any other information on results incl. tables". 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").

4.9.2.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.9.2.19. 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.

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.

4.9.2.20. 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.

Tabella E.46. Field Descriptions

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.
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.

4.9.2.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.9.2.22. Interpretation of results

Provide the qualitative statement with regard to the water solubility according to the author's conclusion. In the supplementary remarks field, indicate if the author's conclusion was changed.

4.9.2.23. Conclusions

Enter any conclusions if applicable.

4.9.2.24. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.9.2.25. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.10. [4.9] Solubility in organic solvents / fat solubility

4.10.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.10.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.10.1.2. Solubility in organic solvents / fat solubility in mg/L at 20°C

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.10.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.10.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.10.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.10.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.47. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.10.2.3. 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.

4.10.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.10.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.10.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.48. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.10.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.10.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.10.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.10.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.49. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.10.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.10.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.10.2.13. Details on methods

Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used.

4.10.2.14. 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.

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.

4.10.2.15. Solubility in organic solvents / fat solubility

Indicate the organic medium used. If necessary, specify the medium in the supplementary remarks field. Enter mean solubility or range if reported so and indicate the temperature in the respective subfield. If necessary, copy this block of fields for each temperature at which the solubility was determined.

Tabella E.50. Field Descriptions

Solubility in	Select from drop-down list.
Solubility (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of solubility (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.

4.10.2.16. Test substance stable

Indicate whether the test substance was stable under the test conditions or not. If applicable, include information on the chemical stability in field "Details on results".

4.10.2.17. Details on results

Give any further relevant information. For example, describe any temperature effects if observed and/or polarity-dependent results if different polarities were used.

As appropriate include tables with raw data and refer to respective table no. (use predefined table(s) if any or adapt table(s) from study report).

4.10.2.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.10.2.19. 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.

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.

4.10.2.20. 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.

Tabella E.51. Field Descriptions

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.
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.

4.10.2.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.10.2.22. Conclusions

Enter any conclusions if applicable.

4.10.2.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.10.2.24. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.11. [4.10] Surface tension

4.11.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.11.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.11.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.11.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.11.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.11.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.11.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.52. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.11.2.3. 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.

4.11.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.11.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.11.2.6. Type of method

Select the test type.

4.11.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.53. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
<p>Deviations from guideline (Deviations)</p>	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.11.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.11.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.11.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.11.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.54. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.11.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.11.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.11.2.14. Details on methods

Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.

4.11.2.15. 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.

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.

4.11.2.16. 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.

Tabella E.55. Field Descriptions

Surface tension (no label)	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. "20", "ca. 20", ">20").
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	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Test substance concentration (Concentration)	Enter numeric value.
Unit of concentration (no label)	Select from drop-down list.

4.11.2.17. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.11.2.18. 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.

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.

4.11.2.19. 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.

Tabella E.56. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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4.11.2.20. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.11.2.21. Conclusions

Enter any conclusions if applicable.

4.11.2.22. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.11.2.23. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.12. [4.11] Flash point

4.12.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.12.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.12.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.12.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.12.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.12.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.12.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.57. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.12.2.3. 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.

4.12.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.12.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.12.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.58. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.12.2.7. 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.

Note: If aerosol was tested, no flash point can be recorded, but flame extension or flame projection. In this case use the template for "Flammability".

4.12.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.12.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.12.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.12.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.59. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.12.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.12.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.12.2.14. 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.

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.

4.12.2.15. Flash point

Enter mean flash point or range if reported so, normally determined at 1013 hPa or at the atmospheric pressure indicated in the respective subfield. If necessary, copy this block of fields for each pressure condition at which the flash point was determined.

Tabella E.60. Field Descriptions

Flash point (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Atmospheric pressure (at)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

4.12.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.12.2.17. 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.

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.

4.12.2.18. 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.

Tabella E.61. Field Descriptions

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.
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.

4.12.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.12.2.20. Conclusions

Enter any conclusions if applicable.

4.12.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.12.2.22. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.13. [4.12] Auto flammability

4.13.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.13.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.13.1.2. Autoflammability / Self-ignition temperature at 101 325 Pa in kelvin (K)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.13.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.13.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.13.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.13.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.62. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.13.2.3. 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.

4.13.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.13.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.13.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.63. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.13.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.13.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.13.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.13.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.64. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.13.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.13.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

4.13.2.13. 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.

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.

4.13.2.14. Autoflammability / Self-ignition temperature

Enter the autoflammability or self-ignition temperature, 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 autoflammability was determined in the respective subfield. If necessary, copy this block of fields for each pressure condition.

Tabella E.65. Field Descriptions

Auto-ignition temperature (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
Atmospheric pressure (at)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>

	(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").
Unit (no label)	Select from drop-down list.

4.13.2.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.13.2.16. 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.

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.

4.13.2.17. 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.

Tabella E.66. Field Descriptions

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.
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.

4.13.2.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.13.2.19. Conclusions

Enter any conclusions if applicable.

4.13.2.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.13.2.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.14. [4.13] Flammability

4.14.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.14.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability

score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.14.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.14.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.14.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

4.14.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.14.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.14.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.67. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.14.2.3. 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.

4.14.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.14.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.14.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.68. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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4.14.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.14.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.14.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.14.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.69. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.14.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.14.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.14.2.13. 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.

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.

4.14.2.14. Solid/liquid: Ignition on contact with air

Indicate result of test for pyrophoric properties, i.e. whether the solid or liquid substance ignites or causes charring when added to an inert carrier and brought into contact with air at ambient temperature for a period of five minutes. Any remarks can be entered in the supplementary remarks field.

4.14.2.15. Solid: Burning time (s)

For solid, provide burning time in sec.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.70. Field Descriptions

<p>Solid: Burning time (s) (no label)</p>	<p>For solid, provide burning time in sec.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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4.14.2.16. Aerosol: Flame extension (cm)

For aerosol, provide the flame extension reported to the nearest cm, if determined with this method.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.71. Field Descriptions

<p>Aerosol: Flame extension (cm) (no label)</p>	<p>For aerosol, provide the flame extension reported to the nearest cm, if determined with this method.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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4.14.2.17. Aerosol: Flame projection (cm)

For aerosol, provide the flame projection reported to the nearest cm, if determined with this method.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.72. Field Descriptions

<p>Aerosol: Flame projection (cm) (no label)</p>	<p>For aerosol, provide the flame projection reported to the nearest cm, if determined with this method.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p>
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	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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4.14.2.18. Gas: Lower explosion limit (%)

For gas, provide lower explosion limit (%).

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. "20", "ca. 20", ">20").

(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".

(iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.73. Field Descriptions

<p>Gas: Lower explosion limit (%) (no label)</p>	<p>For gas, provide lower explosion limit (%).</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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4.14.2.19. Gas: Upper explosion limit (%)

For gas, provide upper explosion limit (%).

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.74. Field Descriptions

<p>Gas: Upper explosion limit (%) (no label)</p>	<p>For gas, provide upper explosion limit (%).</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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4.14.2.20. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.14.2.21. 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.

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.

4.14.2.22. 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.

Tabella E.75. Field Descriptions

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.
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.

4.14.2.23. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.14.2.24. Interpretation of results

Indicate the result of the test conducted according to the method indicated in the field "Guideline" or "Principles of method if other than guideline". If more than one method was used, prepare separate records.

If relevant, describe any preliminary results in the field "Any other information on results incl. tables".

4.14.2.25. Conclusions

Enter any conclusions if applicable.

4.14.2.26. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.14.2.27. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.15. [4.14] Explosiveness

4.15.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.15.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.15.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.15.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.15.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

4.15.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.15.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.15.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.76. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.15.2.3. 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.

4.15.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.15.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.15.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.77. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	

	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.15.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.15.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.15.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.15.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.78. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.15.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.15.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.15.2.13. 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.

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.

4.15.2.14. Explosive under influence of flame

Indicate whether the substance is explosive under influence of flame in a test of thermal sensitivity. In the supplementary remarks field, you can enter any data and remarks, e.g. "expert judgement". If appropriate, include a graph in field "Any other information on results incl. tables".

4.15.2.15. More sensitive to shock than m-dinitrobenzene

Indicate whether the substance is more sensitive to shock than m-dinitrobenzene in a test of mechanical sensitivity with respect to shock. In the supplementary remarks field, you can enter any data and remarks, e.g. "expert judgement". If appropriate, include a graph in field "Any other information on results incl. tables".

4.15.2.16. More sensitive to friction than m-dinitrobenzene

Indicate whether the substance is more sensitive to friction than m-dinitrobenzene in a test of mechanical sensitivity with respect to friction. In the supplementary remarks field, you can enter any data and remarks, e.g. "expert judgement". If appropriate, include a graph in field "Any other information on results incl. tables".

4.15.2.17. Explosive (not specified)

Indicate whether the substance is explosive (not specified) if none of the other explosion indicators apply. In the supplementary remarks field, you can enter any data and remarks, e.g. "expert judgement". If appropriate, include a graph in field "Any other information on results incl. tables".

4.15.2.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.15.2.19. 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.

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.

4.15.2.20. 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.

Tabella E.79. Field Descriptions

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.
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.

4.15.2.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.15.2.22. Conclusions

Enter any conclusions if applicable.

4.15.2.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.15.2.24. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.16. [4.15] Oxidising properties

4.16.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.16.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability

score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.16.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.16.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.16.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

4.16.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.16.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.16.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.80. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.16.2.3. 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.

4.16.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.16.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.16.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.81. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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4.16.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.16.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.16.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.16.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.82. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.16.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.16.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.16.2.13. Contact with

Indicate the chemical with which the test substance was brought in contact. Use separate records for each oxidising or reducing agent tested.

4.16.2.14. Duration of test (contact time)

Indicate duration of test in terms of contact time and unit. If different test runs have different durations, provide the lower and upper limit of the range. For recording different results dependent on different contact time durations, use separate records.

Tabella E.83. Field Descriptions

Duration (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.

4.16.2.15. 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.

4.16.2.16. 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.

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.

4.16.2.17. Test result

Depending on the method used, indicate the parameter measured in the respective subfield, e.g. "temperature rise" or "mean pressure rise time of test mixture". Provide the mean value measured or a range if reported so, and the unit of measurement. As appropriate, enter remarks in the respective subfield.

Copy this block of fields for more than one parameter as appropriate, i.e. to record the maximum burning rate of both the test mixture and the reference mixture.

Tabella E.84. Field Descriptions

Parameter (no label)	Select from drop-down list.
(no label)	Specify here the parameter, if other: was selected in the drop-down list.
Value (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

4.16.2.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.16.2.19. 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.

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.

4.16.2.20. 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.

Tabella E.85. Field Descriptions

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.
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.

4.16.2.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.16.2.22. Interpretation of results

Provide the qualitative statement with regard to the oxidizing properties according to the author's conclusion. In the supplementary remarks field, indicate if the author's conclusion was changed.

4.16.2.23. Conclusions

Enter any conclusions if applicable.

4.16.2.24. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.16.2.25. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.17. [4.16] Oxidation reduction potential

4.17.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.17.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203)
LC50 (48h) = 3.2 mg/l for Oryzias latipes (OECD TG 203)
- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.17.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.17.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.17.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.17.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.17.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.86. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.17.2.3. 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.

4.17.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.17.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.17.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.87. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.17.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.17.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.17.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.17.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.88. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.17.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.17.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.17.2.13. 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.

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.

4.17.2.14. Oxidation reduction potential (OPR) in mV

Provide the mean oxidation reduction potential (OPR) in mV or lower and upper value in case of range and the temperature at which OPR was determined.

Tabella E.89. Field Descriptions

OPR (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Temperature (at)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

4.17.2.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.17.2.16. 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.

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.

4.17.2.17. 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.

Tabella E.90. Field Descriptions

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.
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.

4.17.2.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.17.2.19. Conclusions

Enter any conclusions if applicable.

4.17.2.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.17.2.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.18. [4.17] Stability in organic solvents and identity of relevant degradation products

4.18.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.18.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)

- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.18.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.18.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.18.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.18.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.91. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.18.2.3. 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.

4.18.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.18.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.18.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.92. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.18.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.18.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.18.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.18.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.93. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.18.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.18.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.18.2.13. 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.

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.

4.18.2.14. Test substance stable

Indicate whether the test substance was stable under the test conditions or not. Describe any details on results in field "Remarks: results".

4.18.2.15. Degradation products

Indicate whether degradation products occurred. If yes, provide the identified degradation products in following block of fields. Any further details can be entered in field "Any other information on results incl. tables".

4.18.2.16. Identity of degradation products

Indicate the identity of the degradation 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 degradation products can be provided in field "Any other information on materials and methods incl. tables".

Tabella E.94. Field Descriptions

No.	For easier distinction select a consecutive number for each degradation product from drop-down list if more than one degradation 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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.18.2.17. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.18.2.18. 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.

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.

4.18.2.19. 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.

Tabella E.95. Field Descriptions

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.
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.

4.18.2.20. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.18.2.21. Conclusions

Enter any conclusions if applicable.

4.18.2.22. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.18.2.23. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.19. [4.18] Storage stability and reactivity towards container material

4.19.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.19.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available

- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.19.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.19.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.19.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.19.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.96. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.19.2.3. 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.

4.19.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.19.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.19.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.97. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.19.2.7. Type of method

Indicate which type of method was used. Any additional information can be provided in the supplementary remarks text.

If several data requirements for stability need to be reported, create separate records as appropriate.

4.19.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.19.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.19.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.19.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.98. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.19.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.19.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.19.2.14. Type of container material

Indicate which type of container material was used for the study. If not listed select "other:" and specify. Any additional information can be provided in the supplementary remarks text.

If several materials were tested, create separate records as appropriate.

4.19.2.15. 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 weight or volume.
- TEST CONDITIONS: Report the study duration, the time at sampling, temperature and humidity recorded at regular intervals (e.g. average monthly values or monthly maximum/minimum values). Add any other relevant parameters as appropriate.
- ANALYTICAL METHODS: If the active 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.

4.19.2.16. 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.

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.

4.19.2.17. 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".

4.19.2.18. Degradation products

Indicate whether degradation products occurred. If yes, provide the identified degradation products in following block of fields. Any further details can be entered in field "Any other information on results incl. tables".

4.19.2.19. Identity of degradation products

Indicate the identity of the degradation 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 degradation products can be provided in field "Any other information on materials and methods incl. tables".

Tabella E.99. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.19.2.20. 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.

Several items may be selected by repeating this field.

4.19.2.21. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.19.2.22. 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.

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.

4.19.2.23. 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.

Tabella E.100. Field Descriptions

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.
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.

4.19.2.24. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.19.2.25. Conclusions

Enter any conclusions if applicable.

4.19.2.26. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.19.2.27. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.20. [4.19] Stability: thermal, sunlight, metals

4.20.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.20.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa

- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32×10^{-2} yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.20.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.20.1.3. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

4.20.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.20.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.20.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.101. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.20.2.3. 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.

4.20.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.20.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.20.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.102. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.20.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.20.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.20.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.20.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.103. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.20.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.20.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.20.2.13. Details on methods

Enter any details that could be relevant for evaluating this study summary, particularly if no guideline was used.

4.20.2.14. 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.

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.

4.20.2.15. 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.

4.20.2.16. 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 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".

Tabella E.104. Field Descriptions

Operating temperature (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Enter numeric value.

4.20.2.17. Sublimation

Indicate whether sublimation occurred.

4.20.2.18. Thermal degradation products

Indicate whether degradation products occurred. If yes, provide the identified degradation products in following block of fields. Any further details can be entered in field "Any other information on results incl. tables".

4.20.2.19. Identity of thermal degradation 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".

Tabella E.105. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").

Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.
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4.20.2.20. 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".

4.20.2.21. 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".

4.20.2.22. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.20.2.23. 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.

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.

4.20.2.24. 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.

Tabella E.106. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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4.20.2.25. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.20.2.26. Conclusions

Enter any conclusions if applicable.

4.20.2.27. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.20.2.28. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.21. [4.20] pH

4.21.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.21.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.21.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.107. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	

	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.21.1.3. 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.

4.21.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.21.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.21.1.6. 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. US EPA in addition to OECD guideline).

Tabella E.108. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.21.1.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.21.1.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.21.1.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.21.1.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.109. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.21.1.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.21.1.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.21.1.13. 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.

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.

4.21.1.14. 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.

Tabella E.110. Field Descriptions

pH value	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Temperature	Enter numeric value.
Unit (no label)	Select from drop-down list.
Initial measured concentration (Concentration)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the pH value.

4.21.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.21.1.16. 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.

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.

4.21.1.17. 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.

Tabella E.111. Field Descriptions

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.
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.

4.21.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.21.1.19. Conclusions

Enter any conclusions if applicable.

4.21.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.21.1.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.22. [4.21] Dissociation constant

4.22.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.22.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.22.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.22.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.22.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.22.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.22.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.112. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.22.2.3. 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.

4.22.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.22.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.22.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.113. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.22.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.22.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.22.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.22.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.114. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.22.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.22.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.22.2.13. Details on methods

Provide details on the methods including method of calculation, particularly if no guideline was used.

If applicable, indicate whether there are multiple acidic and/or basic functional groups. Specify the number and type of functional groups.

4.22.2.14. 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.

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.

4.22.2.15. Dissociating properties

Indicate whether the substance has dissociating properties or not.

4.22.2.16. Dissociation constant

If applicable, enter pKa and indicate the temperature in the respective subfield. If only one pKa is given, leave subfield "No." empty. If more than one pKa is recorded, copy this block of fields and select consecutive numbers to distinguish each discrete pKa value measured.

Tabella E.115. Field Descriptions

No.	Select a consecutive number from drop-down list if more than one pKa is recorded.
pKa	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. "20", "ca. 20", ">20").

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Temperature (at)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded value as appropriate, e.g. indicate the functional group.

4.22.2.17. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.22.2.18. 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.

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.

4.22.2.19. 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.

Tabella E.116. Field Descriptions

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.
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.

4.22.2.20. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.22.2.21. Conclusions

Enter any conclusions if applicable.

4.22.2.22. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.22.2.23. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.23. [4.22] Viscosity

4.23.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.23.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.23.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

4.23.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.23.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.23.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.23.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.117. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.23.2.3. 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.

4.23.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.23.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.23.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.118. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

4.23.2.7. Type of method

Select as appropriate.

4.23.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.23.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.23.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.23.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.119. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.23.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.23.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

4.23.2.14. 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.

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.

4.23.2.15. Viscosity

If applicable, enter mean viscosity value or range if reported so and indicate the temperature in the respective subfield. If necessary, copy this block of fields for each temperature.

Tabella E.120. Field Descriptions

Viscosity (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

4.23.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.23.2.17. 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.

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.

4.23.2.18. 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.

Tabella E.121. Field Descriptions

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.
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.

4.23.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.23.2.20. Conclusions

Enter any conclusions if applicable.

4.23.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.23.2.22. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.24. [4.23] Additional physico-chemical information

4.24.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

4.24.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)

- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

4.24.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

4.24.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

4.24.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

4.24.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.122. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	

	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

4.24.2.3. 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.

4.24.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

4.24.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

4.24.2.6. Endpoint investigated

Indicate the endpoint investigated.

4.24.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.123. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

4.24.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

4.24.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

4.24.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

4.24.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.124. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

4.24.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

4.24.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

4.24.2.14. 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.

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.

4.24.2.15. Results

Report the results of the test(s) performed. Include an interpretation of the results in field "Conclusions".

4.24.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

4.24.2.17. 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.

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.

4.24.2.18. 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.

Tabella E.125. Field Descriptions

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.
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.

4.24.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

4.24.2.20. Conclusions

Enter any conclusions if applicable.

4.24.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

4.24.2.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5. [5] Environmental fate and pathways

5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.2. [5.1] Stability

5.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.2.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.2.2. [5.1.1] Phototransformation in air

5.2.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.2.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.2.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.2.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.2.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.2.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.2.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.126. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.2.2.2.3. 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.

5.2.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.2.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.2.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.127. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

5.2.2.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.2.2.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.2.2.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.2.2.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.128. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.2.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.2.2.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.2.2.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties.

5.2.2.2.14. Estimation method (if used)

If the photodegradation was estimated, e.g. the photochemical reaction with OH radicals, include details on the computational method used. Use freetext template as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.

Record the estimated half-life under "Dissipation half-life of parent compound" in the Results section.

Guidance on freetext template:

- Concentration of OH radicals: e.g. "50000 molecules/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"

5.2.2.2.15. Light source

Select light source used.

5.2.2.2.16. Light spectrum: wavelength in nm

Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".

(iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.129. Field Descriptions

<p>Light spectrum: wavelength in nm (no label)</p>	<p>Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.2.2.17. Relative light intensity

Include the relative intensity of light based on sunlight or its range as appropriate.

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. "20", "ca. 20", ">20").

(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".

(iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.130. Field Descriptions

<p>Relative light intensity (no label)</p>	<p>Include the relative intensity of light based on sunlight or its range as appropriate.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p>
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	<p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.2.2.18. 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.

5.2.2.2.19. Details on test conditions

Briefly describe the experimental set-up and procedure used.

5.2.2.2.20. 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.

Tabella E.131. Field Descriptions

Duration	Enter numeric value.
Unit (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Initial measured concentration (Initial conc. measured)	Enter numeric value.
Unit (no label)	Select from drop-down list.

5.2.2.2.21. Reference substance

Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.

5.2.2.2.22. 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.

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.

5.2.2.23. Preliminary study

Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).

5.2.2.24. Test performance - Remarks

Report on any unusual observations during test, deviations from test procedure or any other information affecting results.

5.2.2.25. Spectrum of substance

Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield "Remarks". 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").

Tabella E.132. Field Descriptions

Parameter	<p>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.</p> <p>Explanations:</p> <p>AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time);</p> <p>Cmax: Maximum (peak) concentration;</p> <p>C(time): Maximum concentration at a specified time after administration of a given dose;</p> <p>Tmax: Time to reach peak or maximum concentration following administration</p>
Value	Enter numeric value.

Unit of spectral parameter (no label)	Select unit from drop-down list depending on the spectral parameter selected. E.g. use "nm" for "max lambda" or "L/(mol cm)" or other appropriate unit for "max epsilon". If the unit is not listed, select "other:" and specify.
Remarks	Enter any remarks related to the recorded value as appropriate.

5.2.2.26. % Degradation of test substance

Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.

Tabella E.133. Field Descriptions

% degradation (%Degr.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
St. dev.	Enter numeric value.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.

5.2.2.27. Quantum yield (for direct photolysis)

Give the reaction quantum yield of the test substance (values between 0 and 1).

5.2.2.28. 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.

Tabella E.134. Field Descriptions

Half-life / DT50 (DT50)	
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	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.

5.2.2.2.29. 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".

5.2.2.2.30. Identity of degradation 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".

Tabella E.135. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	

	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.
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5.2.2.2.31. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.2.2.2.32. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.2.2.2.33. 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.

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.

5.2.2.2.34. 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.

Tabella E.136. Field Descriptions

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.
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.

5.2.2.2.35. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.2.2.2.36. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.2.2.2.37. Conclusions

Enter any conclusions if applicable.

5.2.2.2.38. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.2.2.39. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.3. [5.1.2] Hydrolysis

5.2.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.2.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.2.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.2.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.2.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.2.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.2.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.137. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.2.3.2.3. 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.

5.2.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.2.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.138. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

5.2.3.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.2.3.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.2.3.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.2.3.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.139. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.3.2.11. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.2.3.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.2.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.2.3.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties.

5.2.3.2.15. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

5.2.3.2.16. Details on sampling

Enter details on sampling regime and method. Use freetext template as appropriate.

5.2.3.2.17. 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.

5.2.3.2.18. Buffers

Give details on the buffer(s) used for each nominal pH tested; copy any subheading(s) as appropriate for indicating buffers at different pH values. Use freetext template and delete/add elements as appropriate.

5.2.3.2.19. Estimation method (if used)

If an estimation method was used, describe relevant details and input parameters and/or indicate the computer programme used.

5.2.3.2.20. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

If an estimation method was used, describe relevant details and input parameters and/or the computer programme used in field "Principles of method if other than guideline".

5.2.3.2.21. Duration of test

Indicate the test duration, pH and temperature condition and initial test substance concentration at which test was conducted. Copy this block of fields for different test conditions as appropriate.

Tabella E.140. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
pH	Enter the pH value during the test..
Temperature (Temp.)	Enter the temperature with unit (normally °C) during the test.
Initial measured concentration (Initial conc. measured)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.

5.2.3.2.22. Number of replicates

Indicate the number of replicates tested. If different at the different test runs, specify for each pH and temperature.

5.2.3.2.23. Positive controls

Indicate if a positive control (test with a substance with known hydrolysis) was performed. If yes, report the identity of the substance in the supplementary remarks field.

5.2.3.2.24. Negative controls

Indicate if a negative control (test with a stable substance) was performed. If yes, report the identity of the substance in the supplementary remarks field.

5.2.3.2.25. Statistical methods

Enter details on statistical methods used to interpret the results.

5.2.3.2.26. 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.

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.

5.2.3.2.27. Preliminary study

Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).

5.2.3.2.28. Test performance - Remarks

Report on any unusual observations during test, deviations from test procedure or any other information affecting results.

5.2.3.2.29. 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".

5.2.3.2.30. Identity of degradation 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".

Tabella E.141. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").

Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.
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5.2.3.2.31. Details on hydrolysis and appearance of transformation product(s)

Indicate the hydrolysis of the test material and appearance of transformation products, expressed as percentage of the parent substance or applied radioactivity. Use freetext template and delete/add items as appropriate.

Particularly with comprehensive data include a table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

If useful attach a figure in field "Attached background material".

5.2.3.2.32. Total recovery of test substance (in %)

For each pH and temperature condition, indicate the total recovery in % of initial concentration (with standard deviation) or range if reported so. Copy this block of fields as necessary.

Tabella E.142. Field Descriptions

Total recovery (in %) (%Recovery)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
St. dev.	Enter numeric value.
pH	Enter numeric value.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Duration	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.2.3.2.33. Dissipation half-life of parent compound

Indicate the half-lives measured at different pH values and temperature as well as the extrapolated results for 25 degrees Celsius where applicable. Copy this block of fields for each test condition as appropriate.

For robust study summaries or as requested by the regulatory programme, fill in also subfields "Regression equation and r²" and "DT90" (with unit) if available.

Tabella E.143. Field Descriptions

pH	Enter numeric value.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Hydrolysis rate constant	Enter numeric value.
Unit (no label)	Select from drop-down list.
Half-life	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
St. dev.	Enter numeric value.
Type of half-life (Type)	Select from drop-down list.

Remarks (e.g. regression equation, r^2 , DT90)	For robust study summaries or as requested by the regulatory programme, provide the regression equation, r^2 , DT90 (with unit) and/or any relevant remarks.
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5.2.3.2.34. Other kinetic parameters

Describe any other kinetic parameters, if relevant.

5.2.3.2.35. Details on results

Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.

MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field "Identity of transformation products" or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only.

As appropriate attach Figure showing the pathway of phototransformation of the test substance.

SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.

5.2.3.2.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.2.3.2.37. 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.

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.

5.2.3.2.38. 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.

Tabella E.144. Field Descriptions

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.
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.

5.2.3.2.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.2.3.2.40. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.2.3.2.41. Conclusions

Enter any conclusions if applicable.

5.2.3.2.42. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.3.2.43. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.4. [5.1.3] Phototransformation in water

5.2.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.2.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.2.4.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.2.4.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.2.4.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.2.4.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.2.4.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.145. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.2.4.2.3. 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.

5.2.4.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.2.4.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.4.2.6. Study type

Indicate whether direct or indirect photolysis was studied. Note: Any model calculation should be indicated in field "Test result type".

5.2.4.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.146. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
<p>Deviations from guideline (Deviations)</p>	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.2.4.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.2.4.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.2.4.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.2.4.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.147. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.4.2.12. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.2.4.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify

- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.2.4.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.2.4.2.15. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties.

5.2.4.2.16. Analytical method

Indicate which method was used. Copy field for more than one method. If not available from picklist, select "other" and specify.

5.2.4.2.17. Details on sampling

Enter details on sampling regime and method. Use freetext template as appropriate.

5.2.4.2.18. 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.

5.2.4.2.19. Buffers

Using freetext template give details on the buffer(s) used for each nominal pH tested; copy any subheading(s) as appropriate for indicating buffers at different pH values.

5.2.4.2.20. Light source

Select light source used.

5.2.4.2.21. Light spectrum: wavelength in nm

Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.148. Field Descriptions

<p>Light spectrum: wavelength in nm (no label)</p>	<p>Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.4.2.22. Relative light intensity

Include the relative intensity of light based on sunlight or its range as appropriate.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".

(iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.149. Field Descriptions

Relative light intensity (no label)	<p>Include the relative intensity of light based on sunlight or its range as appropriate.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.4.2.23. 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.

5.2.4.2.24. Sensitiser (for indirect photolysis)

Only in the case of an indirect photolysis study indicate what sensitiser was used. For (simulated) natural water or other, give details e.g. on source, pH, dissolved substances e.g. humic acids etc. in subfield "Details on sensitiser". Include concentration (range).

Copy this block of fields as appropriate.

Tabella E.150. Field Descriptions

Type of sensitiser	Select from drop-down list.
Details on sensitiser	Provide details on sensitiser as appropriate.
Concentration of sensitiser	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p>

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.

5.2.4.2.25. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.4.2.26. 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.

Tabella E.151. Field Descriptions

Duration	Enter numeric value.
Unit (no label)	Select from drop-down list.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Initial measured concentration (Initial conc. measured)	Enter numeric value.
Unit (no label)	Select from drop-down list.

5.2.4.2.27. Reference substance

Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.

5.2.4.2.28. Dark controls

Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.

5.2.4.2.29. Computational methods

Enter details on computational methods used to calculate relevant parameters. Use freetext template as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.

5.2.4.2.30. 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.

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.

5.2.4.2.31. Preliminary study

Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).

5.2.4.2.32. Test performance - Remarks

Report on any unusual observations during test, deviations from test procedure or any other information affecting results.

5.2.4.2.33. Spectrum of substance

Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield "Remarks". Copy block of fields for each parameter cited in the study report.

If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield "Remarks").

Tabella E.152. Field Descriptions

Parameter	<p>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.</p> <p>Explanations:</p> <p>AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time);</p> <p>Cmax: Maximum (peak) concentration;</p> <p>C(time): Maximum concentration at a specified time after administration of a given dose;</p>
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	Tmax: Time to reach peak or maximum concentration following administration
Value	Enter numeric value.
Unit of spectral parameter (no label)	Select unit from drop-down list depending on the spectral parameter selected. E.g. use "nm" for "max lambda" or "L/(mol cm)" or other appropriate unit for "max epsilon". If the unit is not listed, select "other:" and specify.
Remarks	Enter any remarks related to the recorded value as appropriate.

5.2.4.2.34. % Degradation of test substance

Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.

Tabella E.153. Field Descriptions

Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.
% degradation (%Degr.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
St. dev.	Enter numeric value.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.

5.2.4.2.35. Quantum yield (for direct photolysis)

For direct photolysis only, give the reaction quantum yield of the test substance (values between 0 and 1).

5.2.4.2.36. Rate constant (for indirect photolysis)

For indirect photolysis only, give photolysis rate constant or range.

Tabella E.154. Field Descriptions

Rate constant (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.

5.2.4.2.37. Dissipation half-life of parent compound

Provide the half-life / DT50 for phototransformation (difference between the irradiated and dark samples) or range as appropriate. Copy this block of fields for recording results at different test conditions.

Tabella E.155. Field Descriptions

Half-life / DT50 (DT50)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.

5.2.4.2.38. Predicted environmental photolytic half-life

Include the predicted environmental photolytic half-life derived from the measured half-life in a sterile buffer solution, if provided. State for which latitude, time of day, season, location etc. the estimation was made.

5.2.4.2.39. 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".

5.2.4.2.40. Identity of degradation 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".

Tabella E.156. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.4.2.41. 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").

Explanations on freetext prompts:

TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.

HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available.

MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field "Identity of transformation products" or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use

predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only.

As appropriate attach Figure showing the pathway of phototransformation of the test substance.

SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.

5.2.4.2.42. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.2.4.2.43. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.2.4.2.44. 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.

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.

5.2.4.2.45. 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.

Tabella E.157. Field Descriptions

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.
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.

5.2.4.2.46. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.2.4.2.47. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.2.4.2.48. Conclusions

Enter any conclusions if applicable.

5.2.4.2.49. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.4.2.50. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.5. [5.1.4] Phototransformation in soil

5.2.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.2.5.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)
- Genetic toxicity:
In vitro:
Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.2.5.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.2.5.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.2.5.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.2.5.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.2.5.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.158. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.2.5.2.3. 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.

5.2.5.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.2.5.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.2.5.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.159. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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5.2.5.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.2.5.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.2.5.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.2.5.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.160. Field Descriptions

Identifier	
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	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.5.2.11. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field "Details on test material".

5.2.5.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.2.5.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.2.5.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties.

5.2.5.2.15. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

5.2.5.2.16. Analytical method

Indicate which method was used. Copy field for more than one method. If not available from picklist, select "other" and specify.

5.2.5.2.17. Details on sampling

Enter details on sampling regime and method. Use freetext template as appropriate.

5.2.5.2.18. 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.

5.2.5.2.19. Details on soil

Using freetext template give details on the soil used. As an alternative option, attach a document e.g. excerpt from the study report.

Note: If applicable, indicate the title and year of the soil classification system used after the respective prompt, i.e. Canadian System of Soil Classification / DIN 19863 (Deutsche Industrie-Norm) / NF X31-107 (Norme francaise) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).

5.2.5.2.20. Light source

Select light source used.

5.2.5.2.21. Light spectrum: wavelength in nm

Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.161. Field Descriptions

<p>Light spectrum: wavelength in nm (no label)</p>	<p>Include wavelength (in nm) range of the indicated light source. Not applicable if light source is sunlight.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.5.2.22. Relative light intensity

Include the relative intensity of light based on sunlight or its range as appropriate.

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. "20", "ca. 20", ">20").
- (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".
- (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").

Tabella E.162. Field Descriptions

<p>Relative light intensity (no label)</p>	<p>Include the relative intensity of light based on sunlight or its range as appropriate.</p>
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	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.2.5.2.23. 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.

5.2.5.2.24. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.5.2.25. Duration of test at given test condition

Indicate the test duration and % moisture, temperature and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.

Tabella E.163. Field Descriptions

Duration	Enter numeric value.
Unit (no label)	Select from drop-down list.
% moisture (%Moisture)	Enter numeric value.
Temperature (Temp.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Initial measured concentration (Initial conc. measured)	Enter numeric value.
Unit (no label)	Select from drop-down list.

5.2.5.2.26. Reference substance

Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.

5.2.5.2.27. Dark controls

Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.

5.2.5.2.28. Computational methods

Enter details on computational methods used to calculate relevant parameters.

5.2.5.2.29. 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.

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.

5.2.5.2.30. Preliminary study

Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).

5.2.5.2.31. Test performance

Report on any unusual observations during test, deviations from test procedure or any other information affecting results.

5.2.5.2.32. Spectrum of substance

Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield "Remarks". Copy block of fields for each parameter cited in the study report.

If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield "Remarks").

Tabella E.164. Field Descriptions

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:
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	<p>AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time);</p> <p>C_{max}: Maximum (peak) concentration;</p> <p>C(time): Maximum concentration at a specified time after administration of a given dose;</p> <p>T_{max}: Time to reach peak or maximum concentration following administration</p>
Value	Enter numeric value.
Unit of spectral parameter (no label)	Select unit from drop-down list depending on the spectral parameter selected. E.g. use "nm" for "max lambda" or "L/(mol cm)" or other appropriate unit for "max epsilon". If the unit is not listed, select "other:" and specify.
Remarks	Enter any remarks related to the recorded value as appropriate.

5.2.5.2.33. % Degradation of test substance

Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.

Tabella E.165. Field Descriptions

% degradation (%Degr.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
St. dev.	Enter numeric value.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.

5.2.5.2.34. Quantum yield (for direct photolysis)

Give the reaction quantum yield of the test substance (values between 0 and 1).

5.2.5.2.35. 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.

Tabella E.166. Field Descriptions

Half-life / DT50 (DT50)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.

5.2.5.2.36. 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".

5.2.5.2.37. Identity of degradation 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".

Tabella E.167. Field Descriptions

No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered.
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	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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.2.5.2.38. 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").

Explanations on freetext prompts:

TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.

HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available.

MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field "Identity of transformation products" or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only.

As appropriate attach Figure showing the pathway of phototransformation of the test substance.

SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.

5.2.5.2.39. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.2.5.2.40. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.2.5.2.41. 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.

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.

5.2.5.2.42. 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.

Tabella E.168. Field Descriptions

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.
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.

5.2.5.2.43. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.2.5.2.44. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.2.5.2.45. Conclusions

Enter any conclusions if applicable.

5.2.5.2.46. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.2.5.2.47. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3. [5.2] Biodegradation

5.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.3.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.3.2. [5.2.1] Biodegradation in water: screening tests

5.3.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.3.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.3.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.3.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.3.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.3.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.3.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.169. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.3.2.2.3. 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.

5.3.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.3.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.2.2.6. Test type

Indicate whether the study was a ready biodegradability test or inherent biodegradability test. If "other:" is selected, specify.

NOTE: Any simulation test should be entered in the respective template.

5.3.2.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.170. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

5.3.2.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.3.2.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.3.2.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.3.2.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.171. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.2.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.3.2.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.3.2.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on study design" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.3.2.2.15. Oxygen conditions

Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.

5.3.2.2.16. 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.

5.3.2.2.17. Details on inoculum

Give details on inoculum as appropriate. Use freetext template and delete/add elements as appropriate.

5.3.2.2.18. Duration of test (contact time)

Indicate duration of test in terms of contact time. If different test runs have different durations, enter lower and upper value in respective subfields.

Tabella E.172. Field Descriptions

Duration (no label)	Enter numeric value(s) (incl. qualifier(s) if any) according to following conventions: (i) Enter single value with no qualifier (left blank) or preceded by ">", ">=" or "ca." in first numeric field; (ii) Enter single value preceded by "<" or "<=" in second numeric field; (iii) Enter range in both numeric fields including qualifier(s) if any.
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Unit (no label)	Select from drop-down list.
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5.3.2.2.19. 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).

Tabella E.173. Field Descriptions

Initial concentration (Initial conc.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Based on	From drop-down list, select the parameter on which the initial concentration is based.

5.3.2.2.20. 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".

5.3.2.2.21. 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.

5.3.2.2.22. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.2.2.23. Reference substance

Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.

5.3.2.2.24. 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.

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.

5.3.2.2.25. Preliminary study

Describe relevant results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).

5.3.2.2.26. 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".

5.3.2.2.27. % Degradation of test substance

Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters.

Note that the degradation at different sampling time points (raw data) should be recorded in below field "Details on results".

NOTE: BOD*100/COD results should be entered in the respective fields below.

Tabella E.174. Field Descriptions

<p>% degradation (%Degr.)</p>	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>
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	(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").
Standard deviation (St. dev.)	Enter numeric value.
Parameter	From drop-down list, select the parameter on which the percentage is based.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.3.2.2.28. Details on results

Record the degradation / elimination kinetics for the different types of test suspensions, i.e. percentage of degradation at different sampling time points.

For robust study summaries or as requested by the regulatory programme, include table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

In field "Attached background material", attach graph(s) with the full degradation or elimination curves for the test and reference substances, the lag phase, degradation phase, the 10-d window and slope.

For tests for ready biodegradability, in which oxygen consumption is used as analytical method (e.g. MITI method), a BOD curve against time should be attached. If requested by the regulatory programme, also include a table on the material (mass) balance of parent compound and transformation products and a table showing the percentage data for degradability measured as BOD, DOC and by specific chemical analysis (see predefined tables).

5.3.2.2.29. BOD5 / COD

For BOD5 tests, copy this block of fields for entering BOD5 and COD values (or ranges if reported so) including the unit, and the ratio BOD5*100/COD (with no unit). If a BOD5/COD ratio is reported, multiply the original value by 100.

Include any raw data in field "Any other information on results incl. tables".

Tabella E.175. Field Descriptions

Parameter (no label)	Select from drop-down list: BOD5, COD or BOD5*100/COD.
Value (no label)	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. "20", "ca. 20", ">20").

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select unit from drop-down list or leave empty if "BOD5*100/COD" was selected as parameter.

5.3.2.2.30. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.3.2.2.31. 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.

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.

5.3.2.2.32. 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.

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.

5.3.2.2.33. 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.

Tabella E.176. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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5.3.2.2.34. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.3.2.2.35. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. Clearly indicate if the criteria used are not consistent with those given by the test guideline.

5.3.2.2.36. Interpretation of results

Indicate overall interpretation of test results with respect to the possible biodegradability as given in the study report. For more detailed discussion of test results, use field "Conclusions".

5.3.2.2.37. Conclusions

Enter any conclusions if applicable.

5.3.2.2.38. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.2.2.39. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.3. [5.2.2] Biodegradation in water and sediment: simulation tests

5.3.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.3.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.3.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.3.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.3.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.3.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.3.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.177. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.3.3.2.3. 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.

5.3.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.3.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.178. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.3.3.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.3.3.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.3.3.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.3.3.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.179. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.3.2.11. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.3.3.2.12. Details on test material

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 HPV, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.3.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.3.3.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on study design" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.3.3.2.15. 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. Include any explanations in the supplementary remarks field as appropriate.

5.3.3.2.16. 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.

5.3.3.2.17. 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.

5.3.3.2.18. 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.

5.3.3.2.19. Details on inoculum

Give details on any other inoculum, e.g. activated sludge if applicable. Use freetext template and delete/add elements as appropriate.

5.3.3.2.20. Duration of test (contact time)

Indicate duration of test in terms of contact time. If different test runs have different durations, enter lower and upper value in respective subfields.

Tabella E.180. Field Descriptions

Duration (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.3.3.2.21. 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).

Tabella E.181. Field Descriptions

Initial concentration (Initial conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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Unit (no label)	Select from drop-down list.
Based on	From drop-down list, select the parameter on which the initial concentration is based.

5.3.3.2.22. 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".

5.3.3.2.23. Details on analytical methods

If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.

Specify methods for water and sediment if applicable.

5.3.3.2.24. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.3.2.25. Reference substance

Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.

5.3.3.2.26. 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.

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.

5.3.3.2.27. 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".

5.3.3.2.28. Material (mass) balance

If applicable, indicate mean total recovery of test material as percentage of applied amount in water and/or sediment +/- standard deviation.

Tabella E.182. Field Descriptions

Mean total recovery in water (% in water)	Enter numeric value.
Standard deviation (St. dev.)	Enter numeric value.
Mean total recovery in sediment (% in sediment)	Enter numeric value.
Standard deviation (St. dev.)	Enter numeric value.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.3.3.2.29. % Degradation of test substance

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".

Tabella E.183. Field Descriptions

% degradation (%Degr.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Standard deviation (St. dev.)	Enter numeric value.
Parameter	From drop-down list, select the parameter on which the percentage is based.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.3.3.2.30. 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.

Tabella E.184. Field Descriptions

Compartment	Select from drop-down list.
Half-life	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
St. dev.	Enter numeric value.
Type of half-life (Type)	Select from drop-down list.
Remarks (e.g. regression equation, r^2 , DT90) (Remarks (e.g. regr. equ., r^2 , DT90))	For robust study summaries or as requested by the regulatory programme, provide the regression equation, r^2 , DT90 (with unit) and/or any relevant remarks.

5.3.3.2.31. Other kinetic parameters

Include any other relevant kinetic parameters if applicable. Select the respective item from the picklist and include the value in the associated remarks field. Copy this field for each parameter to be entered.

5.3.3.2.32. 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".

5.3.3.2.33. Identity of degradation 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".

Tabella E.185. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.3.2.34. 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.

5.3.3.2.35. Evaporation of parent compound

Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field "Details on results" as appropriate.

5.3.3.2.36. Volatile metabolites

Indicate whether volatile metabolites were found or not. Include any explanations in field "Details on results" as appropriate.

5.3.3.2.37. Residues

Indicate whether residues were found or not. Include any explanations in field "Details on results" as appropriate.

5.3.3.2.38. 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) 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.

5.3.3.2.39. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.3.3.2.40. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.3.3.2.41. 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.

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.

5.3.3.2.42. 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.

Tabella E.186. Field Descriptions

Attached document	
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	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.
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.

5.3.3.2.43. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.3.3.2.44. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.3.3.2.45. Conclusions

Enter any conclusions if applicable.

5.3.3.2.46. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.3.2.47. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.4. [5.2.3] Biodegradation in soil

5.3.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.3.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.3.4.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.3.4.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.3.4.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.3.4.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.3.4.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.187. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.3.4.2.3. 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.

5.3.4.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.3.4.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.4.2.6. Test type

Indicate whether the study was a field trial or laboratory study.

5.3.4.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.188. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.3.4.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.3.4.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.3.4.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.3.4.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.189. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.4.2.12. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.3.4.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify

- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.3.4.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.3.4.2.15. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on study design" and "Test performance". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.3.4.2.16. Oxygen conditions

Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.

5.3.4.2.17. Soil classification

Indicate the soil classification system used.

Tabella E.190. Field Descriptions

Soil classification system (no label)	Select as cited in the study report. If not available from picklist, select "other:" and specify.
Year	Indicate year of classification system if available.

5.3.4.2.18. 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.

Tabella E.191. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Soil type	Select from drop-down list.
% clay (Clay %)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
% silt (Silt %)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
% sand (Sand %)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
% total organic carbon (Org. C %)	Enter a numeric value or a range of numeric values according to following conventions:

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	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
pH	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Cation exchange capacity (CEC)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
Bulk density (g/cm ³)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

5.3.4.2.19. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.4.2.20. 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.

Tabella E.192. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Duration	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.

5.3.4.2.21. Initial test substance concentration

Specify initial test concentration applied in the test runs for each soil type, normally based on mg/kg soil dw. If appropriate repeat block of fields and indicate concentration(s) based on g/ha or kg/ha or other (to be specified).

Tabella E.193. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Initial concentration (Initial conc.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.
Based on	From drop-down list, select type of substance on which the initial concentration is based.

5.3.4.2.22. 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".

5.3.4.2.23. 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.

5.3.4.2.24. Experimental conditions

For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.

Tabella E.194. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Temperature (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.
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.
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.

5.3.4.2.25. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.4.2.26. 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.

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.

5.3.4.2.27. 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.

Tabella E.195. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Mean total recovery (%Recovery)	Enter numeric value.
St. dev.	Enter numeric value.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.3.4.2.28. % Degradation of test substance

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.

Tabella E.196. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
% degradation (%Degr.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
St. dev.	Enter numeric value.
Parameter	From drop-down list, select the parameter on which the percentage is based.
Sampling time	Enter numeric value.
Unit sampling time (no label)	Select from drop-down list.

5.3.4.2.29. 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).

Tabella E.197. Field Descriptions

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.
Half-life	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Enter numeric value.
St. dev.	Enter numeric value.
Type of half-life (Type)	Indicate the type of half-life (For first order kinetics DT50 = half-life).
Remarks (e.g. regression equation, r^2 , DT90) (Remarks (e.g. regr. equ., r^2 , DT90))	For robust study summaries or as requested by the regulatory programme, provide the regression equation, r^2 , DT90 (with unit) and/or any relevant remarks.

5.3.4.2.30. 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".

5.3.4.2.31. Identity of degradation 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".

Tabella E.198. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.4.2.32. 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.

5.3.4.2.33. Determination of evaporation of parent compound

Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field "Details on results" as appropriate.

5.3.4.2.34. Determination of volatile metabolites

Indicate whether volatile metabolites were found or not. Include any explanations in field "Details on results" as appropriate.

5.3.4.2.35. Determination of residues

Indicate whether residues were found or not. Include any explanations in field "Details on results" as appropriate.

5.3.4.2.36. 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) 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.

5.3.4.2.37. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

5.3.4.2.38. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.3.4.2.39. 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.

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.

5.3.4.2.40. 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.

Tabella E.199. Field Descriptions

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.
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.

5.3.4.2.41. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.3.4.2.42. Conclusions

Enter any conclusions if applicable.

5.3.4.2.43. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.4.2.44. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.5. [5.2.4] Mode of degradation in actual use

5.3.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.3.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.3.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.200. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate.

	Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.3.5.1.3. 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.

5.3.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.3.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.3.5.1.6. Type of information

Include a short description of the type of information or study. Enter any details in fields "Any other information on materials and methods incl. tables" or "Any other information on results incl. tables" as appropriate..

Fill in fields for Administrative data and Data source as appropriate. If other data from the same study are provided in another chapter, include a reference in field "Same study described in chapter".

5.3.5.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.201. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed);
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	<ul style="list-style-type: none"> - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.3.5.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.3.5.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.3.5.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.3.5.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.202. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.3.5.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable

- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.3.5.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.3.5.1.14. 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.

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.

5.3.5.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.3.5.1.16. 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.

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.

5.3.5.1.17. 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.

Tabella E.203. Field Descriptions

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.
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.

5.3.5.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.3.5.1.19. Conclusions

Enter any conclusions if applicable.

5.3.5.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.3.5.1.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.4. [5.3] Bioaccumulation

5.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.4.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.4.2. [5.3.1] Bioaccumulation: aquatic / sediment

5.4.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.4.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.4.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.4.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.4.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.4.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.4.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.204. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.4.2.2.3. 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.

5.4.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.4.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.4.2.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.205. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

5.4.2.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.4.2.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.4.2.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.4.2.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.206. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.4.2.2.11. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.4.2.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.4.2.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

5.4.2.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.4.2.2.15. Details on sampling

Enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate. For sediment study, distinguish between sampling of sediment, pore water, and overlying water.

5.4.2.2.16. Details on analytical methods

Enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Specify treatment of fish and water samples, including details of preparation, storage, extraction and analytical procedures (and precision) for the test substance and lipid content (if measured).

Copy any subheading(s) for the different matrices as appropriate.

5.4.2.2.17. 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 solutions".

5.4.2.2.18. Details on preparation of test solutions or sediment

Select freetext template for the respective type of study (i.e. aquatic or sediment) and delete/add elements as appropriate.

5.4.2.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

5.4.2.2.20. Details on test organisms

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.2.2.21. Route of exposure

Indicate if exposure was to aquatic medium, sediment or through feed (i.e. dietary exposure).

5.4.2.2.22. Type of sediment (if sediment study)

Indicate whether natural or formulated sediment was used as substrate

5.4.2.2.23. Test type

Select appropriate test type.

5.4.2.2.24. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

5.4.2.2.25. Total exposure / uptake duration

Indicate duration of exposure (uptake).

Tabella E.207. Field Descriptions

Exposure / uptake duration (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.4.2.2.26. Total depuration duration

Indicate duration of depuration.

Tabella E.208. Field Descriptions

Depuration duration (no label)	Enter a numeric value or a range of numeric values according to following conventions:
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	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.4.2.2.27. Hardness

For freshwater tests, indicate water hardness as mg/l calcium carbonate equivalent values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.2.2.28. Test temperature

Indicate test temperature values measured 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.

5.4.2.2.29. pH

Indicate pH values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.2.2.30. Dissolved oxygen

Indicate dissolved oxygen values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.2.2.31. TOC

Indicate TOC (total organic carbon) values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.2.2.32. Salinity

For marine studies, indicate salinity values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.2.2.33. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit, i.e. µg/l, mg/l, g/l, mmol/l, mol/l, µmol/l or other) for all sampling times. As appropriate tabulate nominal vs. measured concentrations; include table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

Use alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

If exposure is through diet, provide the nominal and measured dietary concentrations and the doses applied.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.2.2.34. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.2.2.35. Reference substance (positive control)

Indicate if a positive control was tested, i.e. a reference substance with known bioaccumulation potential. If yes, include the identity of the substance(s) and the concentrations in the supplementary remarks field.

5.4.2.2.36. Details on estimation of bioconcentration

If the intrinsic potential of the test substance for bioconcentration was estimated, indicate physico-chemical properties, experimental toxicokinetic/residue studies or monitoring data the bioconcentration potential was based on.

Indicate the applied software (e.g. BCFWIN, v 2.13) and the basis for BCF calculation (e.g. measured log Pow).

5.4.2.2.37. 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.

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.

5.4.2.2.38. Lipid content

Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment.

Copy this block of fields for specifying the lipid content ratio in % if required.

Tabella E.209. Field Descriptions

Lipid content (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of lipid content (no label)	Select from drop-down list.
Time point	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.4.2.2.39. Bioaccumulation factor

This repeatable block of fields allows to report the steady-state BCFs and/or the kinetic BCFk.

As appropriate or requested by the regulatory programme include table(s) in the rich text field "Any other information on results incl. tables" showing the BCFs measured at different time points and concentrations in the water. 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").

Tabella E.210. Field Descriptions

Concentration in environment / dose level (Conc. in environment / dose)	Give the concentration in surrounding water (and/or sediment, if sediment study) or the dose level applied (if feeding study). If more than one concentration or dose was tested for which different bioaccumulation factors are reported, e.g. for high and low concentration levels, multiply this block of fields and indicate nominal and, if available, measured test concentration(s) (with unit, i.e. µg/l, mg/l, g/l, mmol/l, mol/l, µmol/l, ng/kg, µg/kg or mg/kg sediment dw or other).
Type of bioaccumulation factor (Type)	Indicate the reported bioconcentration factor, i.e. either BCF (bioconcentration factor which accounts for substance intake from the surrounding water only), BFA (bioaccumulation factor which accounts for substance intake from both food and surrounding water), BSAF (biota-sediment accumulation factor), BMF

	(biomagnification factor, i.e. the ratio between the relative concentration in a predatory animal and the concentration in (part of) its prey) or other (to be specified).
Bioaccumulation value (Value)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Basis of bioaccumulation factor (Basis)	From drop-down list, select the basis for the BCF, i.e. expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms (w.w. = wet weight; d.w. = dry weight).
Time of plateau	If applicable, indicate time at which plateau was reached (for tissue concentration).
Unit (no label)	Select from drop-down list.
Calculation basis	If the BCF was not calculated at steady state, select "kinetic:" and briefly specify using the supplementary remarks field (e.g. "kinetic: steady state at 80% of equilibrium).
Remarks	Enter any remarks related to the recorded values as appropriate, e.g. for indicating if BCF is based on parent compound instead of radioactivity.

5.4.2.2.40. Depuration

Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any other percent of residues.

Tabella E.211. Field Descriptions

Elimination	Indicate whether elimination of test substance or metabolites occurred or not.
Endpoint	Indicate to which endpoint type the effect concentration refers, , e.g. DT50.
Depuration time (DT)	Enter numeric value.
Unit (no label)	Select from drop-down list.

5.4.2.2.41. Kinetic parameters

Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.

5.4.2.2.42. Metabolites

If identified, include table(s) in the rich text field "Any other information on results incl. tables" with data on any metabolites of the test substance accumulated in test organisms (total) and specific tissues thereof (e.g. lipid) (at least those, accounting for > 10 % of residues). Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

5.4.2.2.43. Results with reference substance (positive control)

If reference substance(s) was/were tested, indicate whether the results with it/them are valid.

5.4.2.2.44. Details on results

Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that for the reference substance.

5.4.2.2.45. Reported statistics

Indicate the parameters analysed, the statistical method used and the statistical test performed.

5.4.2.2.46. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.4.2.2.47. 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.

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.

5.4.2.2.48. 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.

Tabella E.212. Field Descriptions

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.
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.

5.4.2.2.49. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.4.2.2.50. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.4.2.2.51. Conclusions

Enter any conclusions if applicable.

5.4.2.2.52. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.2.2.53. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.4.3. [5.3.2] Bioaccumulation: terrestrial

5.4.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.4.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.4.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.4.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.4.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.4.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.4.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.213. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.4.3.2.3. 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.

5.4.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.4.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.4.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.214. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.4.3.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.4.3.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.4.3.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.4.3.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.215. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.4.3.2.11. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.4.3.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.4.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPV, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.4.3.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.4.3.2.15. Details on sampling

Enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.

5.4.3.2.16. Details on analytical methods

Enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Specify treatment of animal and soil samples, including details of preparation, storage, extraction and analytical procedures (and precision) for the test substance and lipid content (if measured).

Copy any subheading(s) for the different matrices as appropriate.

5.4.3.2.17. 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".

5.4.3.2.18. Details on preparation and application of test substrate

Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.

5.4.3.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

5.4.3.2.20. 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.

5.4.3.2.21. Total exposure / uptake duration

Indicate duration of exposure (uptake).

Tabella E.216. Field Descriptions

Exposure / uptake duration (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.4.3.2.22. Total depuration duration

Indicate duration of depuration.

Tabella E.217. Field Descriptions

Depuration duration (no label)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit (no label)	Select from drop-down list.

5.4.3.2.23. Nominal and measured concentrations

List nominal and, if available, measured test concentrations in soil and the measured concentrations in tissues (with unit, i.e. mg/kg soil d.w., g/kg soil d.w., g/ha d.w., kg/ha d.w. or other). As appropriate tabulate the data and refer to Table No. (use predefined table if any).

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.3.2.24. Test temperature

Indicate test temperature values measured during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.3.2.25. pH

Indicate pH values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.3.2.26. Moisture

Indicate the soil humidity in % moisture content or g water/100g soil dry weight measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.3.2.27. TOC

Indicate TOC (total organic carbon) values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

5.4.3.2.28. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.3.2.29. 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.

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.

5.4.3.2.30. Lipid content

Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment.

Copy this block of fields for specifying the lipid content ratio in % if required.

Tabella E.218. Field Descriptions

Lipid content (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of lipid content (no label)	Select from drop-down list.
Time point	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.4.3.2.31. Bioconcentration factor

This repeatable block of fields allows to report the steady-state BSAF (biota-to-soil accumulation factor) and/or BCF (bioconcentration factor, where pore water is the basis). Copy this block of fields if more than one value should be entered, e.g. kinetic bioconcentration factors expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms.

Tabella E.219. Field Descriptions

Type of bioconcentration factor (Type)	Indicate the reported bioconcentration factor, i.e. either the steady-state BSAF (biota-to-soil accumulation factor) or BCF (bioconcentration factor, where pore water is the basis).
Bioconcentration factor (Value)	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. "20", "ca. 20", ">20").

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Basis for BCF (Basis)	From drop-down list, select the basis for the BCF, i.e. expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms (w.w. = wet weight; d.w. = dry weight).
Time of plateau	If applicable, indicate time at which plateau was reached (for tissue concentration).
Unit (no label)	Select from drop-down list.
Calculation basis	If the BCF was not calculated at steady state, select "kinetic:" and briefly specify using the supplementary remarks field (e.g. "kinetic: steady state at 80% of equilibrium).
Remarks	Enter any remarks related to the recorded values as appropriate, e.g. for indicating if BCF is based on parent compound instead of radioactivity.

5.4.3.2.32. Depuration

Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any other percent of residues

Tabella E.220. Field Descriptions

Elimination	Indicate whether elimination of test substance or metabolites occurred or not.
Endpoint	Indicate to which endpoint type the effect concentration refers, , e.g. DT50.
Depuration time (DT)	Enter numeric value.
Unit (no label)	Select from drop-down list.

5.4.3.2.33. Kinetic parameters

Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.

5.4.3.2.34. Metabolites

If identified, table(s) with data on any metabolites of the test substance accumulated in test organisms (total), specific tissues thereof (e.g. lipid) should be included (at least those, accounting for > 10 % of residues).

5.4.3.2.35. Details on results

Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that for the reference substance.

5.4.3.2.36. Reported statistics

Indicate the parameters analysed, the statistical method used and the statistical test performed.

5.4.3.2.37. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.4.3.2.38. 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.

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.

5.4.3.2.39. 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.

Tabella E.221. Field Descriptions

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.
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.

5.4.3.2.40. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.4.3.2.41. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.4.3.2.42. Conclusions

Enter any conclusions if applicable.

5.4.3.2.43. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.4.3.2.44. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5. [5.4] Transport and distribution

5.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.5.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.5.2. [5.4.1] Adsorption / desorption

5.5.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.5.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.5.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.5.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.5.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.5.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.5.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.222. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.5.2.2.3. 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.

5.5.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.5.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.2.2.6. Study type

This data entry form is mainly for entering data gained using either the batch equilibrium method or HPLC estimation method. Depending on either of these methods used, some fields or freetext templates are not applicable as indicated in the respective help text.

Qualitative screening tests based on soil thin-layer chromatography should be described in the data entry form "Other distribution data".

5.5.2.2.7. Media

Indicate the medium (i.e. soil, sediment or sewage sludge) for which the adsorption (desorption) determination was made.

For the HPCL estimation method, select "soil/sewage sludge". For any other, select "other" and specify.

5.5.2.2.8. Type of method

Indicate the type of method used regardless of whether it is already specified in the guideline, as this field can be used for query purposes.

5.5.2.2.9. 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. US EPA in addition to OECD guideline).

Tabella E.223. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed);
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	<ul style="list-style-type: none"> - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.5.2.2.10. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.5.2.2.11. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.5.2.2.12. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.5.2.2.13. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.224. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.5.2.2.14. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

5.5.2.2.15. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.5.2.2.16. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.5.2.2.17. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

5.5.2.2.18. Test temperature

Indicate test temperature values measured during test. Include range, mean, standard deviation and unit.

5.5.2.2.19. Details on study design: HPLC method

For the HPLC method only, enter any details on the study design that could be relevant for evaluating this study summary.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.5.2.2.20. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

5.5.2.2.21. Details on sampling

If the amount of test material in the test solutions was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.

5.5.2.2.22. 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.

5.5.2.2.23. Details on matrix

Depending on the test system, i.e. water-soil or water-sediment or water-activated sludge simulation system, include details on either the soil, sediment or sludge solids used in the study. Select respective freetext template and delete/add elements as appropriate. As an alternative option, include or attach an excerpt from the study report.

5.5.2.2.24. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

As appropriate or requested by the regulatory programme include tables in the rich text field "Any other information on results incl. tables" summarising the study design for the adsorption and desorption phase. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.2.2.25. Duration of adsorption equilibration

Indicate sample number (if multiple types of soil/sediment/sludge were used), indicate temperature and initial pH and test substance concentration at which adsorption was conducted and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.

Tabella E.225. Field Descriptions

Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.
Duration	Enter numeric value.

Unit (no label)	Select from drop-down list.
Initial measured concentration (Initial conc. measured)	Enter numeric value.
Unit (no label)	Select from drop-down list.
pH	Enter the initial pH.
Temperature (Temp.)	Enter the temperature with unit (normally °C) during adsorption.

5.5.2.2.26. Duration of desorption equilibration

Indicate sample number (if multiple types of soil/sediment/sludge were used), temperature and amount of test substance concentration in the adsorbed state and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.

Tabella E.226. Field Descriptions

Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.
Duration	Enter numeric value.
Unit (no label)	Select from drop-down list.
Amount of test material present in the adsorbed state (Conc. of adsorbed test mat.)	Enter numeric value.
Unit (no label)	Select from drop-down list.
pH	Enter the pH during desorption.
Temperature (Temp.)	Enter the temperature with unit (normally °C) during desorption.

5.5.2.2.27. Computational methods

Enter details on computational methods used to calculate relevant parameters. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

5.5.2.2.28. 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.

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.

5.5.2.2.29. Adsorption coefficient Koc

Include the adsorption coefficient Koc determined by the batch equilibrium method or estimated using HPLC. If Koc varies depending on test conditions (e.g. different soil samples), include the range of values.

Tabella E.227. Field Descriptions

<p>Adsorption coefficient Koc (no label)</p>	<p>Include the adsorption coefficient Koc determined by the batch equilibrium method or estimated using HPLC. If Koc varies depending on test conditions (e.g. different soil samples), include the range of values.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.5.2.2.30. log Koc

If available, include the log Koc value(s).

Tabella E.228. Field Descriptions

<p>log Koc (no label)</p>	<p>If available, include the log Koc value(s).</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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5.5.2.2.31. Details on results (HPLC method)

For the HPLC method only, include further data as indicated in the freetext template.

5.5.2.2.32. Adsorption and desorption constants

For each soil used provide adsorption and desorption constants including data on the slope of Freundlich adsorption/desorption isotherms (1/N) and regression coefficient of Freundlich equation (R2). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.2.2.33. Recovery of test material

Indicate recovery of test material in supernatant solution and solid phase as well as non-extractable residues after adsorption/desorption, including mean standard deviation. Upload predefined table as appropriate or requested by the regulatory programme in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.2.2.34. Concentration of test substance at end of adsorption equilibration period

Give concentration of test substance in solid and liquid phases at the end of adsorption equilibration period and percent adsorbed test material of applied, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.2.2.35. Concentration of test substance at end of desorption equilibration period

Give concentration of test substance in solid and liquid phases at the end of desorption equilibration period and percent desorbed test material of adsorbed, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.2.2.36. Mass balance (%) at end of adsorption phase

Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of adsorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.

Tabella E.229. Field Descriptions

Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.
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Duration (end of adsorption phase) (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
% adsorption	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

5.5.2.2.37. Mass balance (%) at end of desorption phase

Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of desorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.

Tabella E.230. Field Descriptions

Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.
Duration (end of desorption phase) (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
% desorption	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

5.5.2.2.38. Transformation products

Indicate occurrence of transformation products.

5.5.2.2.39. Identity of degradation 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".

Tabella E.231. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.5.2.2.40. Details on results (Batch equilibrium method)

Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

5.5.2.2.41. Statistics

Indicate the parameters analyzed, the statistical method used and the statistical test performed.

5.5.2.2.42. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.5.2.2.43. 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.

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.

5.5.2.2.44. 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.

Tabella E.232. Field Descriptions

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.
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.

5.5.2.2.45. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.5.2.2.46. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

5.5.2.2.47. Conclusions

Enter any conclusions if applicable.

5.5.2.2.48. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.5.2.2.49. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.3. [5.4.2] Henry's Law constant

5.5.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.5.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)

- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

5.5.3.1.2. Henry's law constant (H) at 20 °C (in Pa m³/mol or dimensionless)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

5.5.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

5.5.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.5.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.5.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.233. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.

Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.
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5.5.3.2.3. 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.

5.5.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.5.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.234. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed);
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	<ul style="list-style-type: none"> - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.5.3.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.5.3.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.5.3.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.5.3.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.235. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.5.3.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable

- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.5.3.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.5.3.2.13. Details on methods

Depending on whether "experimental result" or "estimated by calculation" is indicated in field "Test result type" give relevant details on the methods used to either measure or calculate the Henry's Law constant. Indicate the principles of the method (e.g. OSWER Method or "Bond contribution method") in field "Method: remarks / justification"

5.5.3.2.14. 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.

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.

5.5.3.2.15. Henry's Law constant H

Enter the Henry's Law constant (H) or lower and upper value in case of range. In the respective subfields you may indicate the temperature and pressure at which H was determined. By repeating this block of fields specify both the dimensionless value(s) and the value(s) in the dimensional form as available.

Give any further relevant information in the field "Remarks: results" as appropriate.

Tabella E.236. Field Descriptions

Henry's Law constant H (H)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Temperature (°C) (Temp. (°C))	Enter numeric value.
Atmospheric pressure (Atm. press.)	Enter numeric value.
Unit of pressure (no label)	Select from drop-down list.

5.5.3.2.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.5.3.2.17. 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.

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.

5.5.3.2.18. 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.

Tabella E.237. Field Descriptions

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.
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.

5.5.3.2.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.5.3.2.20. Conclusions

Enter any conclusions if applicable.

5.5.3.2.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.5.3.2.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.4. [5.4.3] Distribution modelling

5.5.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.5.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.5.4.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.238. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M &

	<p>Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate.</p> <p>Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.</p>
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	<p>Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.5.4.1.3. 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.

5.5.4.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.5.4.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.4.1.6. Model

Indicate the estimation/calculation method used.

5.5.4.1.7. Calculation programme

Indicate the applied calculation programme for the distribution model including version number.

5.5.4.1.8. Release year

Give release year of the applied programme version.

5.5.4.1.9. Media

Indicate the media used in the distribution model.

5.5.4.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.5.4.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.239. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.5.4.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.5.4.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.5.4.1.14. Test substance input data

Give test substance input data necessary for the applied model. Use freetext template and delete/add elements as appropriate.

5.5.4.1.15. Environmental properties

Give environmental properties including units used for the applied model. As appropriate upload table(s) for specific defined environmental compartments in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

5.5.4.1.16. 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.

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.

5.5.4.1.17. Air (%)

Give the amount of substance (in percent) estimated to be distributed to air.

5.5.4.1.18. Water (%)

Give the amount of substance (in percent) estimated to be distributed to water.

5.5.4.1.19. Soil (%)

Give the amount of substance (in percent) estimated to be distributed to soil.

5.5.4.1.20. Sediment (%)

Give the amount of substance (in percent) estimated to be distributed to sediment.

5.5.4.1.21. Susp. sediment (%)

Give the amount of substance (in percent) estimated to be distributed to suspended sediment.

5.5.4.1.22. Biota (%)

Give the amount of substance (in percent) estimated to be distributed to biota (e.g. fish).

5.5.4.1.23. Aerosol (%)

Give the amount of substance (in percent) estimated to be distributed as aerosol.

5.5.4.1.24. Other distribution results

Give further results relevant for the specific distribution model.

5.5.4.1.25. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.5.4.1.26. 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.

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.

5.5.4.1.27. 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.

Tabella E.240. Field Descriptions

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.
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.

5.5.4.1.28. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.5.4.1.29. Conclusions

Enter any conclusions if applicable.

5.5.4.1.30. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.5.4.1.31. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.5. [5.4.4] Other distribution data

5.5.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.5.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.5.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.241. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.5.5.1.3. 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.

5.5.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.5.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.5.5.1.6. 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.

5.5.5.1.7. Media

Indicate the media addressed.

5.5.5.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.242. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.5.5.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.5.5.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.5.5.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.5.5.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.243. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.5.5.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.5.5.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.5.5.1.15. 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.

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.

5.5.5.1.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.5.5.1.17. 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.

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.

5.5.5.1.18. 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.

Tabella E.244. Field Descriptions

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.
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.

5.5.5.1.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.5.5.1.20. Conclusions

Enter any conclusions if applicable.

5.5.5.1.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.5.5.1.22. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.6. [5.5] Environmental data

5.6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

5.6.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

5.6.2. [5.5.1] Monitoring data

5.6.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.6.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.6.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.245. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.6.2.1.3. 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.

5.6.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.6.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.6.2.1.6. 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. US EPA in addition to OECD guideline).

Tabella E.246. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
<p>Deviations from guideline (Deviations)</p>	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

5.6.2.1.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.6.2.1.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.6.2.1.9. Type of measurement

Indicate the type of measurement, i.e. background concentration, concentration at contaminated site or other.

5.6.2.1.10. Media

Indicate the medium where the samples were taken from. If different media were examined enter the respective data in separate records.

5.6.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.6.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.247. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.6.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.6.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

5.6.2.1.15. Details on sampling

Briefly describe the location and site where environmental samples were taken and include details on the sampling etc. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report..

5.6.2.1.16. Details on analytical methods

Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report..

5.6.2.1.17. 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.

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.

5.6.2.1.18. Concentration

Enter the concentration or range of concentrations measured in above medium. In the respective subfields, indicate the country and location, whether the measurements are for the substance itself or metabolite(s) and what the period of sampling was (i.e. month/year). In the supplementary remarks field of subfield "Substance or metabolite", the identity of a metabolite should be given if applicable. As appropriate include further explanations in subfield "Remarks", particularly state if a value entered represents the mean or median and/or include the 95 percentile.

Copy this block of fields for indicating several values if necessary.

Tabella E.248. Field Descriptions

Country	Select from drop-down list.
Location	Specify the location.
Substance or metabolite	Select from drop-down list.
Concentration (Conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

Unit of concentration (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded values as appropriate.

5.6.2.1.19. Details on results

Include further details on the measured concentrations as appropriate, i.e. give mean, average values and percentiles. Indicate how measurements below the LOQ and outliers were dealt with, e.g. in calculating 95th percentage values.

Comprehensive data should be tabulated. As appropriate upload predefined table(s) in the rich text field "Any other information on results incl. tables" or 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").

5.6.2.1.20. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.6.2.1.21. 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.

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.

5.6.2.1.22. 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.

Tabella E.249. Field Descriptions

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.
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.

5.6.2.1.23. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.6.2.1.24. Conclusions

Enter any conclusions if applicable.

5.6.2.1.25. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.6.2.1.26. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.6.3. [5.5.2] Field studies

5.6.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.6.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.6.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.250. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.6.3.1.3. 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.

5.6.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.6.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.6.3.1.6. 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. US EPA in addition to OECD guideline).

Tabella E.251. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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5.6.3.1.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.6.3.1.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.6.3.1.9. Type of measurement

Indicate the type of measurement applied.

5.6.3.1.10. Media

Indicate the media investigated.

5.6.3.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.6.3.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.252. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.6.3.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.6.3.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

5.6.3.1.15. 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.

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.

5.6.3.1.16. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.6.3.1.17. 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.

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.

5.6.3.1.18. 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.

Tabella E.253. Field Descriptions

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.
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.

5.6.3.1.19. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.6.3.1.20. Conclusions

Enter any conclusions if applicable.

5.6.3.1.21. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.6.3.1.22. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.7. [5.6] Additional information on environmental fate and behaviour

5.7.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

5.7.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

5.7.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.254. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

5.7.1.3. 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.

5.7.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

5.7.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

5.7.1.6. 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. US EPA in addition to OECD guideline).

Tabella E.255. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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5.7.1.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

5.7.1.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

5.7.1.9. Type of information

Include key words or a short description of the type of information or study. Enter any details in fields "Any other information on materials and methods incl. tables" or "Any other information on results incl. tables" as appropriate.

Fill in fields for Administrative data and Data source as appropriate. If other data from the same study are provided in another chapter, include a reference in field "Same study described in chapter".

5.7.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

5.7.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.256. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

5.7.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

5.7.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

5.7.1.14. 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.

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.

5.7.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

5.7.1.16. 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.

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.

5.7.1.17. 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.

Tabella E.257. Field Descriptions

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.
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.

5.7.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

5.7.1.19. Conclusions

Enter any conclusions if applicable.

5.7.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

5.7.1.21. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6. [6] Ecotoxicological Information

6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.1.1. Justification of PNEC freshwater derivation

Include a justification of the PNEC value derived. Briefly 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 amongst the different taxonomic groups (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.2. Justification of PNEC marine water derivation

Include a justification of the PNEC value derived. Briefly 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 amongst the different taxonomic groups (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.3. Justification of PNEC intermittent releases derivation

Include a justification of the PNEC value derived. Briefly 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 amongst the different taxonomic groups (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.4. Justification of PNEC STP derivation

Include a justification of the PNEC value derived. Briefly describe the rationale for the method applied, specify the data which have been used for the derivation of the PNEC (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.5. Justification of PNEC sediment derivation

Include a justification of the PNEC value derived. Briefly describe the rationale for the method applied, specify the data which have been used for the derivation of the PNEC (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.6. Justification of PNEC soil derivation

Include a justification of the PNEC value derived. Briefly describe the rationale for the method applied, specify the data which have been used for the derivation of the PNEC (the specific selection of the key studies used for each taxonomic group can be reported in the respective endpoint summary record) and justify any assessment factors used, e.g., by referring to the standard procedures of the TGD.

6.1.7. Justification of PNEC oral derivation

Include a justification of the PNEC value derived. Briefly describe the rationale for the method applied, specify the data which have been used for the derivation of the PNEC (the specific selection of the key studies used can be reported in the respective endpoint summary record) and justify any assessment factors used,

e.g., by referring to the standard procedures of the TGD. Also specify the target group to which the PNEC refers (e.g. PNEC oral, predator or PNEC oral, top predator), specify the bioaccumulation potential that triggered the necessary PNEC derivation, and describe the different steps used for the PNEC derivation, including any conversion from NOAELs (toxicity studies) to NOECs and all equations applied.

6.1.8. Discussion

Describe any other relevant criteria as far as not given in the respective fields for the different compartments, and discuss the overall outcome of the PNEC derivations. In this rich text field, you can also insert table(s) either by creating them using the rich text editor or pasting them from a word-processing or html document.

Note: Independent of PNEC values, the field "Discussion" can also be used for summarising the environmental hazard assessment including e.g., discussion of substance-inherent properties that may have an impact on aquatic as well as soil or sediment organisms.

6.1.9. Environmental classification justification

In this rich text field, you can provide any conclusions drawn towards the environmental classification of the substance including the justification for this classification.

6.2. [6.1] Aquatic toxicity

6.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

6.2.2. [6.1.1] Short-term toxicity to fish

6.2.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.258. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.2.2.3. 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.

6.2.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.2.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.259. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.2.2.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.2.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.2.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.2.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.260. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.2.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.2.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.2.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.2.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.2.2.15. 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 appropriate.

6.2.2.2.16. 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.

6.2.2.2.17. 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".

6.2.2.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.2.19. Test organisms (species)

Select appropriate value from picklist. If not available, select "other" and type name of organism (species).

CAVEAT: The following species have been renamed:

- Brachydanio rerio

- Salmo gairdneri

If one of these names is reported, select the appropriate picklist value which indicates both the new name plus, in parentheses, the name as reported, i.e.

- Danio rerio (reported as Brachydanio rerio)

- Oncorhynchus mykiss (reported as Salmo gairdneri)

(Note: The outdated names are kept in the picklist for data migration reasons.)

6.2.2.20. Details on test organisms

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.21. Test type

Select appropriate test type.

6.2.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.261. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.

Remarks	Enter any remarks related to the total exposure duration.
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6.2.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.2.26. Hardness

For freshwater tests, 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.

6.2.2.27. 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.

6.2.2.28. pH

Indicate pH 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.

6.2.2.29. 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.

6.2.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.2.33. 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.

6.2.2.2.34. 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.

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.

6.2.2.2.35. Effect concentrations

Report the LC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.262. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "LLx" (Effect loading rate resulting in x% mortality) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20").

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (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 "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as mortality or behaviour, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.2.2.36. Details on results

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").

As appropriate also attach a figure with growth curves in field "Attached background material".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.2.37. Results with reference substance (positive control)

If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide mortality, LC50 data and other relevant information.

Use freetext template and delete/add elements as appropriate.

6.2.2.2.38. 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.

6.2.2.2.39. Any other information on results incl. tables

In this field, you can enter any other information on results, 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.

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.

6.2.2.2.40. 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.

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.

6.2.2.2.41. 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.

Tabella E.263. Field Descriptions

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.
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.

6.2.2.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.2.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.2.2.44. Conclusions

Enter any conclusions if applicable.

6.2.2.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.2.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.3. [6.1.2] Long-term toxicity to fish

6.2.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used,

test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.264. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.3.2.3. 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.

6.2.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.3.2.6. Test type

Select the appropriate life stage / endpoint studied (e.g. "early-life stage: reproduction, toxicity").

Select "adult fish: toxicity" for long-term toxicity tests performed according to the modified OECD 204 or similar. Note that the regulatory programme may request to record the Prolonged Toxicity Test (14-day Study) conducted according to OECD Guideline 204 using the template "Short-term toxicity to fish".

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

6.2.3.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.265. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.2.3.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.3.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.3.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.3.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.266. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.3.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.3.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.3.2.15. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.3.2.16. 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 appropriate.

6.2.3.2.17. 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.

6.2.3.2.18. 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".

6.2.3.2.19. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.20. Test organisms (species)

Select appropriate value from picklist. If not available, select "other" and type name of organism (species).

CAVEAT: The following species have been renamed:

- *Brachydanio rerio*

- *Salmo gairdneri*

If one of these names is reported, select the appropriate picklist value which indicates both the new name plus, in parentheses, the name as reported, i.e.

- *Danio rerio* (reported as *Brachydanio rerio*)

- *Oncorhynchus mykiss* (reported as *Salmo gairdneri*)

(Note: The outdated names are kept in the picklist for data migration reasons.)

6.2.3.2.21. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.22. Test type

Select appropriate test type.

6.2.3.2.23. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.3.2.24. Limit test

Indicate if the experiment was a limit test.

6.2.3.2.25. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

For life cycle studies, also indicate the duration of exposure of parental fish (F0) and subsequent generation(s), i.e. F1, F2.

Tabella E.267. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.

Remarks	Enter any remarks related to the total exposure duration.
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6.2.3.2.26. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.3.2.27. Hardness

For freshwater tests, 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.

6.2.3.2.28. 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.

6.2.3.2.29. pH

Indicate pH 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.

6.2.3.2.30. 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.

6.2.3.2.31. Salinity

For marine studies, indicate salinity 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.

6.2.3.2.32. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.33. Details on test conditions

Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.34. 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.

6.2.3.2.35. 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.

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.

6.2.3.2.36. Effect concentrations

Report the EC50, NOEC, LOEC or other effect levels with 95% conf. limits if appropriate. Copy this field block for entering more than one effect level if necessary.

Tabella E.268. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "ELx" (Effect loading rate giving x% effect) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=".

	(iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as "mortality" or "adult mortality" (if life cycle study), which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. organism stage for effect, dry or wet weight, total length or standard fork length, time for start until end of hatching, etc.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.3.2.37. Details on results

Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Particularly with comprehensive data, include table(s) with raw data in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1"). Narrative accompanying such tabular data can then be rather short and should not repeat what is presented in the table(s). The same holds true if any figure is attached in field "Attached background material".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.38. 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.

6.2.3.2.39. 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.

6.2.3.2.40. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.3.2.41. 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.

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.

6.2.3.2.42. 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.

Tabella E.269. Field Descriptions

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.
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.

6.2.3.2.43. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.3.2.44. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.3.2.45. Conclusions

Enter any conclusions if applicable.

6.2.3.2.46. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.3.2.47. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.4. [6.1.3] Short-term toxicity to aquatic invertebrates

6.2.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.4.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.4.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.4.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.4.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.4.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.270. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.4.2.3. 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.

6.2.4.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.4.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.4.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.271. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.2.4.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.4.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.4.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.4.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.272. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.4.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.4.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.4.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.4.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.4.2.15. 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 appropriate.

6.2.4.2.16. 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.

6.2.4.2.17. 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".

6.2.4.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.4.2.19. Test organisms (species)

Select appropriate value from picklist. If not available, select "other" and type name of organism (species).

6.2.4.2.20. Details on test organisms

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.4.2.21. Test type

Select appropriate test type.

6.2.4.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.4.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.4.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.273. Field Descriptions

Duration (no label)	Enter numeric value.
(no label)	Select from drop-down list.
Unit (Remarks)	Enter any remarks related to the total exposure duration.

6.2.4.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.4.2.26. Hardness

For freshwater tests, 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.

6.2.4.2.27. 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.

6.2.4.2.28. pH

Indicate pH 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.

6.2.4.2.29. 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.

6.2.4.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.4.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.4.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.4.2.33. 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.

6.2.4.2.34. 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.

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.

6.2.4.2.35. Effect concentrations

Report the LC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.274. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "LLx" (Effect loading rate resulting in x% mortality) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as mortality or behaviour, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.

Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.
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6.2.4.2.36. Details on results

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 tables with raw data and refer to respective table no. (use predefined table(s) if any or adapt table(s) from study report). As appropriate attach figure with growth curves.

6.2.4.2.37. Results with reference substance

If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide mortality, EC50/LC50 data and other relevant information.

Use freetext template and delete/add elements as appropriate.

6.2.4.2.38. Reported statistics and error estimates

Indicate the parameters analyzed, 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.

6.2.4.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.4.2.40. 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.

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.

6.2.4.2.41. 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.

Tabella E.275. Field Descriptions

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.
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.

6.2.4.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.4.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.4.2.44. Conclusions

Enter any conclusions if applicable.

6.2.4.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.4.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.5. [6.1.4] Long-term toxicity to aquatic invertebrates

6.2.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.5.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.5.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.5.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.5.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.5.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.5.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.276. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.5.2.3. 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.

6.2.5.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.5.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.5.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.277. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
<p>Deviations from guideline (Deviations)</p>	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.2.5.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.5.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.5.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.5.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.278. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.5.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".

- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.5.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.5.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.5.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.5.2.15. 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 appropriate.

6.2.5.2.16. 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.

6.2.5.2.17. 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".

6.2.5.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

Note: Enter "Mysidopsis bahia" under new name "Americamysis bahia".

6.2.5.2.20. Details on test organisms

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.21. Test type

Select appropriate test type.

6.2.5.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.5.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.5.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.279. Field Descriptions

Duration (no label)	Enter numeric value.
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Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.2.5.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.5.2.26. Hardness

For freshwater tests, 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.

6.2.5.2.27. 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.

6.2.5.2.28. pH

Indicate pH 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.

6.2.5.2.29. 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.

6.2.5.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.5.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.33. 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.

6.2.5.2.34. 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.

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.

6.2.5.2.35. Effect concentrations

Report the EC50, NOEC, LOEC or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.280. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "LLx" (Effect loading rate resulting in x% mortality) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
Basis for effect	Select effect parameter such as reproduction, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. organism stage for effect, dry or wet weight, length, etc.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.5.2.36. Details on results

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.37. 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.

6.2.5.2.38. 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.

6.2.5.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.5.2.40. 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.

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.

6.2.5.2.41. 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.

Tabella E.281. Field Descriptions

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.
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.

6.2.5.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.5.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.5.2.44. Conclusions

Enter any conclusions if applicable.

6.2.5.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.5.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.6. [6.1.5] Toxicity to aquatic algae and cyanobacteria

6.2.6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.6.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.6.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.6.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.6.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.6.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.6.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.282. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.6.2.3. 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.

6.2.6.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.6.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.6.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.283. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.2.6.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.6.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.6.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.6.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.284. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.6.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.6.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.6.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.6.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.6.2.15. 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 appropriate.

6.2.6.2.16. 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.

6.2.6.2.17. 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".

6.2.6.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.6.2.19. Test organisms (species)

Select appropriate value from picklist. If not available, select "other" and type name of organism (species).

CAVEAT: The following species have been renamed:

- Raphidocelis subcapitata
- Selenastrum capricornutum
- Scenedesmus subspicatus

If one of these names is reported, select the appropriate picklist value which indicates both the new name plus, in parentheses, the name as reported, i.e.

- Desmodesmus subspicatus (reported as Scenedesmus subspicatus)
- Pseudokirchnerella subcapitata (reported as Raphidocelis subcapitata)
- Pseudokirchnerella subcapitata (reported as Selenastrum capricornutum)

(Note: The outdated names are kept in the picklist for data migration reasons.)

6.2.6.2.20. 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.

6.2.6.2.21. Test type

Select appropriate test type.

6.2.6.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.6.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.6.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.285. Field Descriptions

Duration (no label)	Enter numeric value.
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Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.2.6.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.6.2.26. Hardness

For freshwater tests, 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.

6.2.6.2.27. 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.

6.2.6.2.28. pH

Indicate pH 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.

6.2.6.2.29. 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.

6.2.6.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.6.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.6.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.6.2.33. 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.

6.2.6.2.34. 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.

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.

6.2.6.2.35. Effect concentrations

Report the EC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.286. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "ELx" (Effect loading rate giving x% effect) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20").

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (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 "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as growth rate, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field. For algal tests where EC values were corrected by the light inhibition effect of a coloured substance, include a note "corrected for colour effect".
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.6.2.36. Details on results

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.6.2.37. 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.

6.2.6.2.38. 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.

6.2.6.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.6.2.40. 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.

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.

6.2.6.2.41. 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.

Tabella E.287. Field Descriptions

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.
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.

6.2.6.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.6.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.6.2.44. Conclusions

Enter any conclusions if applicable.

6.2.6.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.6.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.7. [6.1.6] Toxicity to aquatic plants other than algae

6.2.7.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.7.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.7.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.7.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.7.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.7.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.7.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.288. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.7.2.3. 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.

6.2.7.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.7.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.7.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.289. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.2.7.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.7.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.7.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.7.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.290. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.7.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.7.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.7.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.7.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.7.2.15. 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 appropriate.

6.2.7.2.16. 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.

6.2.7.2.17. 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".

6.2.7.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.7.2.19. Test organisms (species)

Select appropriate value from picklist. If not available, select "other" and type name of organism (species).

6.2.7.2.20. 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.

6.2.7.2.21. Test type

Select appropriate test type.

6.2.7.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.7.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.7.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.291. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.2.7.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.7.2.26. Hardness

For freshwater tests, 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.

6.2.7.2.27. 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.

6.2.7.2.28. pH

Indicate pH 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.

6.2.7.2.29. 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.

6.2.7.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.7.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.7.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.7.2.33. 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.

6.2.7.2.34. 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.

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.

6.2.7.2.35. Effect concentrations

Report the EC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.292. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "ELx" (Effect loading rate giving x% effect) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as growth rate, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.
Remarks (e.g. 95% CL)	

For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.
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6.2.7.2.36. Details on results

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").

As appropriate also attach a figure with growth curves in field "Attached background material".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

6.2.7.2.37. 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.

6.2.7.2.38. 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.

6.2.7.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.7.2.40. 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.

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.

6.2.7.2.41. 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.

Tabella E.293. Field Descriptions

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.
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.

6.2.7.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.7.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.7.2.44. Conclusions

Enter any conclusions if applicable.

6.2.7.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.7.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.8. [6.1.7] Toxicity to microorganisms

6.2.8.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.8.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.8.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.2.8.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.8.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.8.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.8.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.294. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.8.2.3. 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.

6.2.8.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.8.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.8.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.295. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.2.8.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.8.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.8.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.8.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.296. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.8.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.8.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.8.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.8.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.8.2.15. 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 appropriate.

6.2.8.2.16. 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.

6.2.8.2.17. 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".

6.2.8.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.8.2.19. Test organisms (species)

Select species or type of activated sludge used as inoculum. If not available, select "other" and specify.

6.2.8.2.20. Details on inoculum

Give details on inoculum as appropriate.

6.2.8.2.21. Test type

Select appropriate test type.

6.2.8.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.8.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.8.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.297. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.2.8.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.8.2.26. Hardness

For freshwater tests, 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.

6.2.8.2.27. 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.

6.2.8.2.28. pH

Indicate pH 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.

6.2.8.2.29. 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.

6.2.8.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.8.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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 alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.8.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.8.2.33. 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.

6.2.8.2.34. 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.

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.

6.2.8.2.35. Effect concentrations

Report the EC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.298. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (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 "no data" if not known.
Effect concentration type (Conc. based on)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.

	Select "no data" if effect concentration type is not known.
Basis for effect	Select effect parameter such as respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.8.2.36. Details on results

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").

As appropriate also attach a figure with growth curves in field "Attached background material".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.8.2.37. 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.

6.2.8.2.38. 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.

6.2.8.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.8.2.40. 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.

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.

6.2.8.2.41. 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.

Tabella E.299. Field Descriptions

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.
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.

6.2.8.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.8.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.8.2.44. Conclusions

Enter any conclusions if applicable.

6.2.8.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.8.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.9. [6.1.8] Toxicity to other aquatic organisms

6.2.9.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.2.9.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)

- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.2.9.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.2.9.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.2.9.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.2.9.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.300. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.2.9.2.3. 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.

6.2.9.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.2.9.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.2.9.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.301. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.

Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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6.2.9.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.2.9.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.2.9.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.2.9.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.302. Field Descriptions

Identifier	
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	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.2.9.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available

- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.2.9.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.2.9.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields,

particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.2.9.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.2.9.2.15. 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 appropriate.

6.2.9.2.16. 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.

6.2.9.2.17. 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".

6.2.9.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.9.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

6.2.9.2.20. Details on test organisms

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.9.2.21. Test type

Select appropriate test type.

6.2.9.2.22. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.2.9.2.23. Limit test

Indicate if the experiment was a limit test.

6.2.9.2.24. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.303. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.2.9.2.25. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.2.9.2.26. Hardness

For freshwater tests, 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.

6.2.9.2.27. 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.

6.2.9.2.28. pH

Indicate pH 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.

6.2.9.2.29. 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.

6.2.9.2.30. Salinity

For marine studies, indicate salinity 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.

6.2.9.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations and refer to Table no. (use predefined table if any).

6.2.9.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.9.2.33. 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.

6.2.9.2.34. 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.

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.

6.2.9.2.35. Effect concentrations

Report the LC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.304. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list. Note: When the results are expressed in terms of the loading rate of water accommodated fraction (WAF) causing a particular effect, use respective endpoints, i.e. "LLx" (Effect loading rate resulting in x%

	mortality) or "NOELR" / "LOELR" (No observed / lowest observed effect loading rate).
Effect concentration (Effect conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
Basis for effect	Select effect parameter such as mortality or behaviour, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.2.9.2.36. Details on results

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. As appropriate attach figure with growth curves.

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.9.2.37. 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.

6.2.9.2.38. 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.

6.2.9.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.2.9.2.40. 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.

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.

6.2.9.2.41. 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.

Tabella E.305. Field Descriptions

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.
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.

6.2.9.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.2.9.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.2.9.2.44. Conclusions

Enter any conclusions if applicable.

6.2.9.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.2.9.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.3. [6.2] Sediment toxicity

6.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.306. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.3.2.3. 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.

6.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.3.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.307. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.3.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.3.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.3.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.3.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.308. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.3.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.3.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.3.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.3.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.3.2.15. 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 appropriate.

Note: Indicate which concentrations were measured if not all.

6.3.2.16. 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.

6.3.2.17. Vehicle

Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field "Details on sediment and application".

6.3.2.18. Details on sediment and application

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.3.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

6.3.2.20. 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.

6.3.2.21. Study type

Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicing a near-natural environment with ambient climatic conditions) or field study (using natural populations).

6.3.2.22. Test duration type

Indicate test duration type, i.e. either short-term or long-term. If a test was designed to determine both short and long term effects, create two different records for each test duration type.

6.3.2.23. Test type

Select appropriate test type.

6.3.2.24. Water media type

Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.

6.3.2.25. Type of sediment

Indicate whether natural or formulated sediment was used as substrate

6.3.2.26. Limit test

Indicate if the experiment was a limit test.

6.3.2.27. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.309. Field Descriptions

Duration (no label)	Enter numeric value.
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Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.3.2.28. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.

6.3.2.29. Hardness

For freshwater tests, 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.

6.3.2.30. Test temperature

Indicate test temperature values measured in the treatment and control vessels 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.

6.3.2.31. pH

Indicate pH values measured in the treatment and control vessels 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.

6.3.2.32. 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.

6.3.2.33. Salinity

For marine studies, indicate salinity 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.

6.3.2.34. Ammonia

Indicate the ammonia concentration measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

6.3.2.35. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.3.2.36. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.3.2.37. 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.

6.3.2.38. 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.

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.

6.3.2.39. Effect concentrations

Report the EC50, NOEC, LOEC or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.310. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
Basis for effect	Select effect parameter such as development, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. "mean development rate, male and female midges pooled".
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.3.2.40. Details on results

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.3.2.41. 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.

6.3.2.42. 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.

6.3.2.43. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.3.2.44. 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.

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.

6.3.2.45. 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.

Tabella E.311. Field Descriptions

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.
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.

6.3.2.46. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.3.2.47. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.3.2.48. Conclusions

Enter any conclusions if applicable.

6.3.2.49. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.3.2.50. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4. [6.3] Terrestrial toxicity

6.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

6.4.2. [6.3.1] Toxicity to soil macroorganisms except arthropods

6.4.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.312. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.2.2.3. 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.

6.4.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.2.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.313. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.4.2.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.2.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.2.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.2.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.314. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.2.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.2.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

6.4.2.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.2.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.4.2.2.15. 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 appropriate.

Note: Indicate which concentrations were measured if not all. As applicable, provide information for soil, stock and/or spray solution.

6.4.2.2.16. 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.

6.4.2.2.17. 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".

6.4.2.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.2.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

6.4.2.2.20. Animal group

Indicate the animal group, e.g. "annelids" for a test with a worm species. Helpful for searching purposes.

6.4.2.2.21. 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.

6.4.2.2.22. Study type

Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicing a near-natural environment with ambient climatic conditions) or field study (using natural populations).

6.4.2.2.23. Test duration type

Indicate test duration type, i.e. either short-term or long-term. If a test was designed to determine both short and long term effects, create two different records for each test duration type.

6.4.2.2.24. Substrate type

Select type of substrate.

6.4.2.2.25. Limit test

Indicate if the experiment was a limit test.

6.4.2.2.26. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.315. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.4.2.2.27. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.

6.4.2.2.28. Test temperature

Indicate test temperature values measured in the treatment and control vessels during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

6.4.2.2.29. pH

Indicate the pH of the soil and water at the start and end of the test. 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.

6.4.2.2.30. Moisture

Indicate the water content of the soil at the start and end of the test. 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.

6.4.2.2.31. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.2.2.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.2.2.33. 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.

6.4.2.2.34. 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.

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.

6.4.2.2.35. Effect concentrations

Report the LC50 (for acute tests) or EC50, NOEC, LOEC or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.316. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
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, e.g. "inability to dig into soil"..
Remarks (e.g. 95% CL)	

	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.
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6.4.2.2.36. Details on results

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.2.2.37. 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.

6.4.2.2.38. 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.

6.4.2.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.2.2.40. 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.

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.

6.4.2.2.41. 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.

Tabella E.317. Field Descriptions

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.
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.

6.4.2.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.2.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.2.2.44. Conclusions

Enter any conclusions if applicable.

6.4.2.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.2.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.3. [6.3.2] Toxicity to terrestrial arthropods

6.4.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.318. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.3.2.3. 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.

6.4.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.3.2.6. Application method

Select as method of application as appropriate. If not available from picklist, select "other" and specify.

6.4.3.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.319. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.4.3.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.3.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.3.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.3.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.320. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.3.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.3.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.4.3.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.3.2.15. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.4.3.2.16. 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 appropriate.

Note: Indicate which concentrations were measured if not all. As applicable, provide information for soil, stock and/or spray solution.

6.4.3.2.17. 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.

6.4.3.2.18. 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".

6.4.3.2.19. Details on preparation and application of test substrate

Depending on the type of study, select appropriate freetext template (e.g. Honeybees: contact study) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.3.2.20. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

6.4.3.2.21. 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.

6.4.3.2.22. 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.

6.4.3.2.23. Study type

Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicing a near-natural environment with ambient climatic conditions) or field study (using natural populations).

6.4.3.2.24. Test duration type

Where applicable, indicate test duration type, i.e. either short-term or long-term. If a test was designed to determine both short and long term effects, create two different records for each test duration type.

6.4.3.2.25. Limit test

Indicate if the experiment was a limit test.

6.4.3.2.26. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.321. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.4.3.2.27. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.

6.4.3.2.28. Test temperature

Indicate test temperature values measured in the treatment and control vessels during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). As applicable indicate the life-stage in parentheses if different temperatures were used e.g. in case of predator and parasite studies. Example: 20+/-1°C (adults), 25+/-1.5°C (larval exposure), 18+/-1°C (pupal development), 25+/-1°C (fecundity).

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.

6.4.3.2.29. pH (if soil study)

If study with soil-dwelling arthropods, indicate the pH of the soil and water at the start and end of the test. 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.

6.4.3.2.30. Humidity

If study with soil-dwelling arthropods, indicate the water content of the soil at the start and end of the test.

If study with above-ground arthropods, indicate the relative humidity of the experimental room during the test measured in the treatment and control vessels. Include range, mean, standard deviation and unit. As applicable indicate the life-stage in parentheses if different humidities were used e.g. in case of predator and parasite studies.

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.

6.4.3.2.31. Photoperiod and lighting

If study with above-ground arthropods, indicate the photoperiod and lighting intensity in the experimental room during the test measured in the treatment and control vessels. Include range, mean, standard deviation and unit. As applicable indicate the life-stage in parentheses if different lighting conditions were used e.g. in case of predator and parasite studies.

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.

6.4.3.2.32. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit) or, if contact or oral study with honeybees, the nominal and measured doses applied. As appropriate tabulate nominal vs. measured concentrations 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.3.2.33. Details on test conditions

Depending on the type of study, select appropriate freetext template (i.e. soil or above-ground arthropods) 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.3.2.34. 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.

6.4.3.2.35. 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.

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.

6.4.3.2.36. Effect concentrations

Report the LC50 (for acute tests) or EC50, NOEC, LOEC or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.322. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
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.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.4.3.2.37. Details on results

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 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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.3.2.38. 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.

6.4.3.2.39. 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.

6.4.3.2.40. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.3.2.41. 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.

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.

6.4.3.2.42. 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.

Tabella E.323. Field Descriptions

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.
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.

6.4.3.2.43. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.3.2.44. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.3.2.45. Conclusions

Enter any conclusions if applicable.

6.4.3.2.46. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.3.2.47. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.4. [6.3.3] Toxicity to terrestrial plants

6.4.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.4.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.4.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.4.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.4.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.4.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.324. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.4.2.3. 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.

6.4.4.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.4.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.4.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.325. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.4.4.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.4.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.4.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.4.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.326. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.4.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.4.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.4.4.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.4.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.4.4.2.15. 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 appropriate.

Note: Indicate which concentrations were measured if not all. As applicable, provide information for soil, stock and/or spray solution.

6.4.4.2.16. 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.

Note: Indicate whether the analytical method is for analysis of soil, stock and/or spray solution as applicable.

6.4.4.2.17. 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".

6.4.4.2.18. Details on 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.4.2.19. 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.

Tabella E.327. Field Descriptions

Species	Select from drop-down list.
Plant group	Select from drop-down list.
Details on test organism (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.

6.4.4.2.20. Study type

Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicing a near-natural environment with ambient climatic conditions) or field study (using natural populations).

6.4.4.2.21. Test duration type

Indicate test duration type, i.e. either short-term or long-term. If a test was designed to determine both short and long term effects, create two different records for each test duration type.

6.4.4.2.22. Test type

Select appropriate test type.

6.4.4.2.23. Substrate type

Select type of substrate.

6.4.4.2.24. Limit test

Indicate if the experiment was a limit test.

6.4.4.2.25. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

For life cycle studies, also indicate the duration of exposure of parental fish (F0) and subsequent generation(s), i.e. F1, F2.

Tabella E.328. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.

Remarks

Enter any remarks related to the total exposure duration.

6.4.4.2.26. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate.

6.4.4.2.27. Test temperature

Indicate test temperature values measured in the treatment and control vessels during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

6.4.4.2.28. pH

Indicate the pH of the soil at the start and end of the test. 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.

6.4.4.2.29. Moisture

Indicate the water content of the soil at the start and end of the test. 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.

6.4.4.2.30. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). Indicate which concentration was measured, e.g. highest test concentration.

6.4.4.2.31. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Note: If any information is specific to a given species (in case several species are recorded in one record), add the species name in parentheses, e.g. "- No. of seeds per container: 50 (*Sorghum vulgare*); 100 (*Oryza sativa*)"

6.4.4.2.32. 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.

6.4.4.2.33. 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.

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.

6.4.4.2.34. Effect concentrations

Report the NOEC, ECx or ERx (x% effect concentration or effect (field application) rate) or other effect levels with 95% conf. limits if available. Copy this field block for entering more than one effect level if necessary.

Tabella E.329. Field Descriptions

Species	Select from drop-down list.
Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list. Note: Units given in "ppm" should be converted.
Basis for concentration (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 "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
Basis for effect	Select effect parameter such as growth, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field,

	e.g. fresh or dry shoot weight, shoot height etc.(for growth), chlorosis, mortality, plant development abnormalities etc. (for phytotoxicity).
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.4.4.2.35. Details on results

Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate, e.g. copy headings for including data on different species. 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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.4.2.36. 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.

6.4.4.2.37. 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.

6.4.4.2.38. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.4.2.39. 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.

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.

6.4.4.2.40. 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.

Tabella E.330. Field Descriptions

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.
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.

6.4.4.2.41. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.4.2.42. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.4.2.43. Conclusions

Enter any conclusions if applicable.

6.4.4.2.44. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.4.2.45. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.5. [6.3.4] Toxicity to soil microorganisms

6.4.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.5.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.5.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.5.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.5.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.5.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.5.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.331. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.5.2.3. 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.

6.4.5.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.5.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.5.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.332. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	

	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.4.5.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.5.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.5.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.5.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.333. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.5.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.5.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.4.5.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.5.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.4.5.2.15. 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 appropriate.

6.4.5.2.16. 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.

6.4.5.2.17. 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".

6.4.5.2.18. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.5.2.19. Test organisms (species)

Select "soil" if soil samples were used as inoculum. Otherwise select "other" and specify.

6.4.5.2.20. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.334. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.4.5.2.21. Test temperature

Indicate test temperature values measured in the treatment and control vessels during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. "see table no. 2") if the test conditions are presented in tabular form in the rich text editor field.

6.4.5.2.22. Moisture content

Indicate the water content of the soil at the start and end of the test. 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.

6.4.5.2.23. Organic carbon content (% dry weight)

Indicate the organic matter or organic carbon content of the soil sample in % dry weight.

6.4.5.2.24. Nitrogen content (% dry weight)

Indicate the nitrogen content of the soil sample in % dry weight.

6.4.5.2.25. Nominal and measured concentrations

Indicate the test concentrations with unit and note whether they are nominal or measured. Normally the concentrations of the test substance added to soil are calculated, e.g. assuming uniform incorporation to a depth of 5 cm and a soil bulk density of 1.5.

6.4.5.2.26. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.5.2.27. 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.

6.4.5.2.28. 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.

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.

6.4.5.2.29. Effect concentrations

Report the EC50 or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.335. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
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Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
Basis for effect	Select effect parameter such as respiration rate, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. "based on carbon dioxide / oxygen release".
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.4.5.2.30. 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-reponse curve.

6.4.5.2.31. Results with reference substance

Indicate whether the results with the reference substance(s) are valid.

6.4.5.2.32. 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.

6.4.5.2.33. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.5.2.34. 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.

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.

6.4.5.2.35. 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.

Tabella E.336. Field Descriptions

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.
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.

6.4.5.2.36. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.5.2.37. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.5.2.38. Conclusions

Enter any conclusions if applicable.

6.4.5.2.39. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.5.2.40. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.6. [6.3.5] Toxicity to birds

6.4.6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.6.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.6.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.6.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.6.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.6.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.6.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.337. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.6.2.3. 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.

6.4.6.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.6.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.6.2.6. Test type

Indicate test type.

6.4.6.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.338. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.4.6.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.6.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.6.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.6.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.339. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.6.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.6.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.4.6.2.14. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.6.2.15. Dose method

Select as appropriate. If not available from picklist, select "other" and specify.

6.4.6.2.16. Analytical monitoring

Indicate whether test substance was monitored in the test medium. If yes, specify in field "Details on preparation and monitoring of diet".

6.4.6.2.17. Vehicle

Indicate whether vehicle was used, e.g. to facilitate mixing with feed.

6.4.6.2.18. Details on preparation and analysis of diet

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.

6.4.6.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

6.4.6.2.20. 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.

6.4.6.2.21. Limit test

Indicate if the experiment was a limit test.

6.4.6.2.22. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.340. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.4.6.2.23. Post exposure observation period

Indicate the post-observation period (with unit) during which "clean" feed was administered.

6.4.6.2.24. No. of animals per sex per dose

Indicate number of animals used per dose group. State if different numbers were used and reason why.

6.4.6.2.25. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

6.4.6.2.26. Nominal and measured doses / concentrations

List nominal and, if available, measured dose levels or test concentrations (with unit). Indicate if nominal in diet, nominal in water, actual ingested, actual in diet, measured concentration in diet, etc. Provide range, median, mean, SD as applicable. As appropriate tabulate nominal vs. measured concentrations and refer to Table no..

6.4.6.2.27. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.28. Details on examinations and observations

Indicate the time schedule and further details for the examinations and observations performed (use separate freetext 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 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.29. Details on reproductive parameters

For avian reproduction toxicity test, indicate the reproductive parameters examined.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.30. 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.

6.4.6.2.31. 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.

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.

6.4.6.2.32. Effect levels

Report the LC50, LD50, NOEC or LOEC for all health (and reproductive) parameters depending on the study type. Copy this field block for entering more than one effect level if necessary.

Tabella E.341. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>

	(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").
Unit of effect level (no label)	Select from drop-down list.
Effect concentration type (no label)	Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field. Select "no data" if effect concentration type is not known.
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".
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.4.6.2.33. 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.

6.4.6.2.34. 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 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.35. 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 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.36. 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.

6.4.6.2.37. Further details on results

Report any other relevant results. Compare the results for the test substance with that for the reference substance.

6.4.6.2.38. Reported statistics and error estimates

Indicate the parameters analysed, the statistical method used and the statistical test performed.

6.4.6.2.39. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.6.2.40. 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.

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.

6.4.6.2.41. 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.

Tabella E.342. Field Descriptions

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.
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.

6.4.6.2.42. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.6.2.43. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.6.2.44. Conclusions

Enter any conclusions if applicable.

6.4.6.2.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.6.2.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.7. [6.3.6] Toxicity to other above-ground organisms

6.4.7.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

6.4.7.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

6.4.7.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

6.4.7.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

6.4.7.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.4.7.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.4.7.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.343. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.4.7.2.3. 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.

6.4.7.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.4.7.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.4.7.2.6. 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. US EPA in addition to OECD guideline).

Tabella E.344. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.4.7.2.7. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.4.7.2.8. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.4.7.2.9. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.4.7.2.10. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.345. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.4.7.2.11. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.4.7.2.12. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.4.7.2.13. Details on properties of test surrogate or analogue material

ONLY if another substance, i.e. analogue or surrogate (e.g. degradation/transformation product) was used as test material, enter any relevant details on the properties of this substance that may possibly affect the test performance, particularly physico-chemical properties.

Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding templates and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

6.4.7.2.14. Analytical monitoring

Indicate whether test substance was monitored in the test solutions.

For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.

6.4.7.2.15. 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 appropriate.

6.4.7.2.16. Details on analytical methods

Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.

6.4.7.2.17. Vehicle

Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility.

6.4.7.2.18. Details on test medium and application

Enter any details that could be relevant for evaluating this study summary. For tests with honeybees use freetext template and delete/add elements as appropriate. For other tests briefly describe the method of preparation and application of the test material indicating the most relevant details.

6.4.7.2.19. Test organisms (species)

Select species from picklist. If not available, select "other" and enter name of organism (species).

Note that studies with terrestrial arthropods should be recorded using the template "Toxicity to terrestrial arthropods".

6.4.7.2.20. 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.

6.4.7.2.21. Study type

Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicing a near-natural environment with ambient climatic conditions) or field study (using natural populations).

6.4.7.2.22. Limit test

Indicate if the experiment was a limit test.

6.4.7.2.23. Total exposure duration

Include numeric value and unit of duration in the respective subfields. Any range reported because several test runs were summarised or any relevant remark should be entered in subfield "Remarks".

Tabella E.346. Field Descriptions

Duration (no label)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

6.4.7.2.24. Post exposure observation period

Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.

6.4.7.2.25. Test temperature

Indicate test temperature values measured in the treatment and control vessels during test. Include range, mean, standard deviation and unit. As applicable indicate the life-stage in parentheses if different temperatures were used e.g. in case of predator and parasite studies. Example: 20+/-1°C (adults), 25+/-1.5°C (larval exposure), 18+/-1°C (pupal development), 25+/-1°C (fecundity).

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.

6.4.7.2.26. Humidity

Indicate the relative humidity of the experimental room during the test measured in the treatment and control vessels. Include range, mean, standard deviation and unit. As applicable indicate the life-stage in parentheses if different humidities were used e.g. in case of predator and parasite studies.

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.

6.4.7.2.27. Photoperiod and lighting

Indicate the photoperiod and lighting intensity in the experimental room during the test measured in the treatment and control vessels. Include range, mean, standard deviation and unit. As applicable indicate the life-stage in parentheses if different lighting conditions were used e.g. in case of predator and parasite studies.

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.

6.4.7.2.28. Nominal and measured concentrations

List nominal and, if available, measured test concentrations (with unit). As appropriate tabulate nominal vs. measured concentrations and refer to Table No. (use predefined table if any).

6.4.7.2.29. Details on test conditions

Provide any other relevant details on test conditions.

6.4.7.2.30. 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.

6.4.7.2.31. 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.

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.

6.4.7.2.32. Effect concentrations

Report the EC50, NOEC or other effect levels. Copy this field block for entering more than one effect level if necessary.

Tabella E.347. Field Descriptions

Exposure duration (Duration)	Enter numeric value.
Unit (no label)	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect concentration (Effect conc.)	Enter a numeric value or a range of numeric values according to following conventions:

	<p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of effect concentrations (no label)	Select from drop-down list.
Basis for concentration (Nominal/Measured)	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighed average = TWA), measured (not specified), acid equivalent or estimated. Select "no data" if not known.
Effect concentration type (Conc. based on)	<p>Indicate whether the concentration is based on the test material (test matl), active ingredient (act. ingr.), element, dissolved (if inorganic non-metal), labile/free (if metal) or other (specify). Further information can be given in the supplementary remarks field.</p> <p>Select "no data" if effect concentration type is not known.</p>
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.
Remarks (e.g. 95% CL)	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits and/or any relevant short remarks.

6.4.7.2.33. Details on results

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.

For acute oral tests with honeybees, provide information about palatability of the treated diet, rate of consumption of diet in treated and untreated groups.

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.7.2.34. 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.

6.4.7.2.35. 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.

6.4.7.2.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.4.7.2.37. 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.

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.

6.4.7.2.38. 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.

Tabella E.348. Field Descriptions

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.
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.

6.4.7.2.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.4.7.2.40. Validity criteria fulfilled

Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. 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.

6.4.7.2.41. Conclusions

Enter any conclusions if applicable.

6.4.7.2.42. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.4.7.2.43. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.5. [6.4] Biological effects monitoring

6.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.349. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.5.1.3. 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.

6.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.5.1.6. Type of information

Include key words or a short description of the type of information or study. Enter any details in fields "Any other information on materials and methods incl. tables", "Any other information on results incl. tables" and/or "Remarks: any other information" as appropriate.

Fill in fields for Administrative data and Data source as appropriate. If other data from the same study are provided in another chapter, include a reference in field "Same study described in chapter".

6.5.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.350. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.5.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.5.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.5.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.5.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.351. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.5.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.5.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.5.1.14. 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.

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.

6.5.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.5.1.16. 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.

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.

6.5.1.17. 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.

Tabella E.352. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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6.5.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.5.1.19. Conclusions

Enter any conclusions if applicable.

6.5.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.5.1.21. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.6. [6.5] Biotransformation and kinetics

6.6.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.6.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.6.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.353. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.6.1.3. 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.

6.6.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.6.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.6.1.6. Type of medium

Indicate type of medium, i.e. aquatic or terrestrial.

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" and/or "Remarks: any other information" as appropriate. As an option you can include table(s).

6.6.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.354. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p>

	<p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

6.6.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.6.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.6.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.6.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.355. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.6.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.6.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

6.6.1.14. 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.

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.

6.6.1.15. Transformation products

Indicate occurrence of transformation products. If yes, specify the transformation products in the following field.

Enter any further results in field "Remarks: results" as appropriate.

6.6.1.16. Identity of degradation 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".

Tabella E.356. Field Descriptions

No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered.
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	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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.6.1.17. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.6.1.18. 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.

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.

6.6.1.19. 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.

Tabella E.357. Field Descriptions

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.
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.

6.6.1.20. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.6.1.21. Conclusions

Enter any conclusions if applicable.

6.6.1.22. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.6.1.23. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.7. [6.6] Additional ecotoxicological information

6.7.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

6.7.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

6.7.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.358. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

6.7.1.3. 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.

6.7.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

6.7.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

6.7.1.6. Type of information

Include key words or a short description of the type of information or study. Enter any details in fields "Any other information on materials and methods incl. tables" and/or "Any other information on results incl. tables" as appropriate.

Fill in fields for Administrative data and Data source as appropriate. If other data from the same study are provided in another chapter, include a reference in field "Same study described in chapter".

6.7.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.359. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

6.7.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

6.7.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

6.7.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

6.7.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.360. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

6.7.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

6.7.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

6.7.1.14. 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.

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.

6.7.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

6.7.1.16. 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.

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.

6.7.1.17. 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.

Tabella E.361. Field Descriptions

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.
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.

6.7.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

6.7.1.19. Conclusions

Enter any conclusions if applicable.

6.7.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

6.7.1.21. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7. [7] Toxicological information

7.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.1.1. Discussion

Describe any other relevant criteria as far as not given in the distinct fields (e.g. specify the key studies used for the dose descriptors including the target organs identified) and discuss the overall outcome of the DN(M)EL derivations. In this rich text field, you can also insert table(s) either by creating them using the rich text editor or pasting them from a word-processing or html document.

Note: Independent of DN(M)EL values, the field "Discussion" can also be used for summarising endpoint data, which do not fit in any specific endpoint summary record or include an appraisal of several different endpoints.

7.1.2. Discussion

Describe any other relevant criteria as far as not given in the distinct fields (e.g. specify the key studies used for the dose descriptors including the target organs identified) and discuss the overall outcome of the DN(M)EL derivations. If DN(M)EL values are available for sensitive sub-populations, document and discuss these values. In this rich text field, you can also insert table(s) either by creating them using the rich text editor or pasting them from a word-processing or html document.

Note: Independent of DN(M)EL values, the field "Discussion" can also be used for summarising endpoint data, which do not fit in any specific endpoint summary record or include an appraisal of several different endpoints.

7.2. [7.1] Toxicokinetics, metabolism and distribution

7.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.2.1.1. Discussion

Provide any introductory remarks and/or overall discussion of the endpoints summarised in the subsections subsumed under this section.

7.2.2. [7.1.1] Basic toxicokinetics

7.2.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.2.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.2.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.2.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.2.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.362. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M &

	<p>Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate.</p> <p>Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.</p>
Year	<p>Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".</p>
Title	<p>Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).</p>
Bibliographic source	<p>Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	<p>Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.</p>
Report no.	<p>Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.</p>
Owner company	<p>Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.</p>
Company study no.	<p>Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.</p>
Report date	<p>Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.</p>

7.2.2.2.3. 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.

7.2.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.2.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.2.2.2.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.2.2.2.7. Objective of study

Indicate the purpose of the study. The field is repeatable. Select the respective toxicokinetic aspect(s) investigated.

7.2.2.2.8. 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. US EPA in addition to OECD guideline).

Tabella E.363. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed);
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	<ul style="list-style-type: none"> - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.2.2.2.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.2.2.2.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.2.2.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.2.2.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.364. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.2.2.2.13. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material". In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.

7.2.2.2.14. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable

- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.2.2.2.15. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.2.2.2.16. Species

Select name of species. For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select "other" and specify.

7.2.2.2.17. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.2.2.2.18. Sex

Select as appropriate. If different sexes were used in multiple test runs recorded in the same record, select "male/female" and differentiate in field "Doses / concentrations".

7.2.2.2.19. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.2.2.2.20. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.2.2.2.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.2.2.2.22. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.23. Duration and frequency of treatment / exposure

Indicate duration and frequency of application, e.g. "single application" or "multiple application: 14 days, 2 doses per day, 5 days per week".

7.2.2.2.24. Doses / concentrations

Indicate the dose groups and state if the the doses/concentrations were "nominal in diet", "actual ingested", "nominal conc.", actual conc." etc. and give both nominal and actual values as appropriate.

In case of a robust study summary or as requested by the regulatory programme, also provide a detailed table on the animal assignment in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.25. No. of animals per sex per dose

Enter value or specify according to dose if different number of animals per dose, e.g. "4 in each dose group with single application; 2 f and 4 m in multiple application group".

In case of a robust study summary, include animal numbers per sex in table on animal assignment.

7.2.2.2.26. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify.

7.2.2.2.27. Positive control

Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No.

7.2.2.2.28. Details on study design

Include further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.29. Details on dosing and sampling

Include details on dosing and sampling. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

7.2.2.2.30. Statistics

List parameters that were analysed by which test methods.

7.2.2.2.31. 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.

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.

7.2.2.2.32. Preliminary studies

Briefly describe the results of preliminary study or studies if any.

7.2.2.2.33. Absorption

Briefly describe absorption. Include degree of absorption in %. In case of a robust study summary, include a relating excretion of radioactivity (in urine, feces, etc.) to sampling time. Refer to respective table no. (use predefined table if any).

7.2.2.2.34. Distribution in tissues

For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues/organs. Include a brief narrative. In case of a robust study summary, also include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.35. Transfer into organs

Indicate the transfer of the radiolabelled test substance into organs. Copy this block of fields for each transfer type and/or different test runs if applicable.

Tabella E.365. Field Descriptions

Test No.	Select a consecutive test number from drop-down list if more than one test runs are reported.
Transfer type	Select type of transfer (e.g. "blood/brain transfer") from picklist.
Observation	Select the qualitative description (e.g. "distinct transfer") that characterises the observed transfer of radiolabelled test substance into the brain or spinal cord or into the placenta and on the secretion of radioactivity via the gastric mucosa, respectively. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field.

7.2.2.2.36. Excretion

For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues and excreta including total recovery. Include a brief narrative. In case of a robust study summary, also include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.37. Toxicokinetic parameters

Select toxicokinetic parameter from picklist and enter the corresponding value(s) with unit in the related text field.

Examples: (i) Half-life 1st: 23.4 hrs (male, single administration study); (ii) C(time): 88 µg/l at 40 hrs

Copy this block of fields for each parameter. If multiple test runs are recorded, enter test numbers in subfield "Test No.".

Tabella E.366. Field Descriptions

Test No.	Select a consecutive test number from drop-down list if more than one test runs are reported.
Parameter (no label)	Select parameter from drop-down list. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration

7.2.2.2.38. Metabolites identified

Indicate whether metabolites were identified.

7.2.2.2.39. Details on metabolites

List the metabolites identified, include percent of radioactive dose given, where they were identified, when, if applicable, how they were identified, if applicable, how much parent was present in the excreta.

In case of a robust study summary, also include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

When available, include summary of metabolic pathways and attach figures in field "Attached background material". Mention which are major vs. minor pathways. Attach the submitter's postulated pathway as a figure.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.40. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.2.2.2.41. 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.

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.

7.2.2.2.42. 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.

Tabella E.367. Field Descriptions

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.
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.

7.2.2.2.43. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.2.2.2.44. Interpretation of results

Indicate overall interpretation of test results with regard to the bioaccumulation potential as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

7.2.2.2.45. Conclusions

Enter any conclusions if applicable.

7.2.2.2.46. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.2.2.47. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.2.3. [7.1.2] Dermal absorption

7.2.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.2.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32×10^{-2} yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.2.3.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.2.3.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.2.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.2.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.2.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.368. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.2.3.2.3. 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.

7.2.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.2.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.2.3.2.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Details on in vitro test system (if applicable)". If a specific template for in vitro assays is provided include the data in that template instead.

7.2.3.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.369. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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7.2.3.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.2.3.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.2.3.2.10. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material". In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.

7.2.3.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.2.3.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.370. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.2.3.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.2.3.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.2.3.2.15. Species

Select as appropriate. For in vitro tests, indicate the species used as source of the skin samples. If not available from picklist, select "other" and specify.

Note: If human skin was used in an in vitro test, comment on ethical approval in field "Details on in vitro test system".

7.2.3.2.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.2.3.2.17. Sex

Select as appropriate.

7.2.3.2.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.

- 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).

7.2.3.2.19. Type of coverage

Select as appropriate. If not available from picklist, select "other" and specify.

7.2.3.2.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.2.3.2.21. Duration of exposure

Indicate the time interval between application and removal of test preparation by skin washing, e.g. "6 hours". Describe when termination occurred. Explain if some groups were terminated at wash and some were washed, then terminated later.

7.2.3.2.22. Doses

As appropriate enter text or use freetext template and delete/add elements. Indicate the nominal and, if available, the actual doses including unit applied to the test animals (e.g. "0.0X, 0.X, and X.0 µg ai/X cm² skin over all duration periods"). Also state the dose volume (e.g. in ml/cm²) and provide the rationale for dose selection (explain, e.g., anticipated dermal deposition in the field). Modify any unit in the freetext template as appropriate.

For i.v. dosing, specify whether the same animal is used for intravenous and dermal dosing.

In case of a robust study summary or as requested by the regulatory programme, also provide a detailed table on the animal assignment in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.3.2.23. No. of animals per group

Indicate number of animals per group of one sex, i.e. each test preparation and each scheduled termination time. If numbers differ, specify, e.g. "4 in all groups but one; 3 in 2 mg/cm² group scheduled for termination at 48 hours"

7.2.3.2.24. Control animals

Indicate whether control groups were used and specify or comment in supplementary remarks field as appropriate.

7.2.3.2.25. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

DOSE PREPARATION: e.g., combining appropriate amounts of the radioactive and non-radioactive formulation, and water and thoroughly mixing.

APPLICATION OF DOSE: provide details on how the dose was applied (e.g., X µL was applied and spread evenly across the surface of the skin site using (e.g., a glass rod). The glass rod used to apply the dose was (e.g. rinsed with X ml of methanol, wiped with a gauze pad and the rinse and wipe collected for analysis).).

TEST SITE:

- Preparation of test site: e.g. shaved (or discuss); shaved area washed with XXXX. Abrasion?

- Area of exposure: expressed in cm²

- % coverage / - Type of cover / wrap if used: provide data on the percentage and type of coverage (e.g., The dosing enclosure was covered by (e.g., a nonocclusive filter paper cover attached using rubber cement)).

SITE PROTECTION / USE OF RESTRAINERS FOR PREVENTING INGESTION: indicate if restrainers (spacers) were used and what type (e.g. Elizabethan collar placed on each animal's neck).

REMOVAL OF TEST SUBSTANCE: Describe timing, removal of apparatus, washing procedures, other approaches used (e.g., tape stripping), etc.

SAMPLE COLLECTION: Describe sample collection during the exposure period and until termination of study (e.g. urine, faeces, blood, expired air), procedures for termination, analysis of organs (e.g., Skin from application site; blood; residual urine; residual carcass; cover, cage washings and other potentially contaminated equipment)

7.2.3.2.26. Details on in vitro test system (if applicable)

In the case of in vitro testing give details on the skin preparation. Include source of skin (State what type of skin was used, i.e. viable or non-viable skin, epidermal membranes or split / full thickness skin). Give details on how skin was prepared and any treatment(s) (heat separation, chemical or enzymatic separation). Include data on any check for membrane integrity.

Briefly describe the principles of the assay. Note: Enter information on duration, application, sampling and analysis in the respective fields.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.3.2.27. 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.

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.

7.2.3.2.28. Signs and symptoms of toxicity

Indicate whether signs and symptoms of toxicity were observed or not. If yes, describe the effects at the different doses in the supplementary remarks field. In addition or as an alternative option, include a table and refer to the respective table no.

7.2.3.2.29. Dermal irritation

Indicate whether any dermal irritation were observed or not. If yes, describe the effects and at what doses in the supplementary remarks field.

7.2.3.2.30. Absorption in different matrices

Include the dose recovery in the various matrices, i.e. amount of compound in each sample (% of dose applied). The dose recovery should include skin wash, cover and enclosure (if applicable), carbon filter (if applicable), tape stripping (if applicable), urine, cage wash and wipe , faeces, expired air, carcass and skin application site. Use freetext template delete/add elements as appropriate.

For very comprehensive data refer to summary tables for each dose level (e.g. predefined table). Include table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.3.2.31. Total recovery

Include the total recovery and information on its validity. Use freetext template delete/add elements as appropriate.

- Total recovery: e.g., Total amounts of radioactivity in samples were reported as a percentage of the total dose (or discuss).
- Limit of detection (LOD): e.g., Limits of detection were established as follows: range µg/g sample for the low dose group, range µg/g sample for the medium dose group and range µg/g sample for the high dose group. [or note if this data not reported]
- Quantification of values below LOD or LOQ: describe how values below LOD or LOQ were quantified (i.e. values < LOD = 1/2 LOD or 0)

7.2.3.2.32. Percutaneous absorption rate

Include the most appropriate mean dermal absorption value. Copy this block of fields for different dose groups as appropriate.

Tabella E.371. Field Descriptions

Time point	Include hours after application when the residues were determined, e.g. "120 h".
Dose group (Dose)	Indicate the group for which the absorption value is provided, e.g. "2 g/cm ² skin". As appropriate several groups may be included, for example if absorption was less than a certain percentage in all groups.
Absorption rate (%) (Absorption (%))	<p>Include the respective value or range of values if given e.g. for several groups. Include qualifiers as appropriate. Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Remarks	Remarks: For any comments as appropriate.

7.2.3.2.33. Conversion factor human vs. animal skin

If a conversion factor was derived to account for the difference in permeability between human and animal skin, provide this factor including details on the calculation basis, e.g. based on differences in absorption rates or in flux as applicable.

7.2.3.2.34. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.2.3.2.35. 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.

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.

7.2.3.2.36. 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.

Tabella E.372. Field Descriptions

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.
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.

7.2.3.2.37. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.2.3.2.38. Conclusions

Enter any conclusions if applicable.

7.2.3.2.39. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.2.3.2.40. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3. [7.2] Acute Toxicity

7.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)
- Genetic toxicity:
In vitro:
Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.3.1.2. Acute toxicity: oral

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.3.1.3. Acute toxicity: dermal

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.3.1.4. Acute toxicity: inhalation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.3.1.5. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.3.1.6. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.3.2. [7.2.1] Acute toxicity: oral

7.3.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.3.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.3.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.373. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.3.2.1.3. 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.

7.3.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.3.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.2.1.6. Test type

If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies.

If neither of these test types applies, either leave field empty or use "other:".

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.3.2.1.7. Limit test

Indicate if the experiment was a limit test.

7.3.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.374. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.3.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.3.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.3.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.3.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.375. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.3.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.3.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.3.2.1.15. 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.3.2.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.3.2.1.17. Sex

Select as appropriate.

7.3.2.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.3.2.1.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.3.2.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.3.2.1.21. 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.

7.3.2.1.22. Doses

Include the doses including unit administered to the test animals, "5, 50, 500 and 2000 mg/kg bw". As appropriate include notes in parentheses, e.g. "(male)".

7.3.2.1.23. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.2.1.24. Control animals

Indicate whether concurrent control group was used.

7.3.2.1.25. 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.

7.3.2.1.26. Statistics

Indicate the method of calculating the LD50 or other.

7.3.2.1.27. 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.

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.

7.3.2.1.28. Preliminary study (if fixed dose study)

In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.

7.3.2.1.29. 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".

Tabella E.376. Field Descriptions

Sex	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select from drop-down list.
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>

	(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").
Remarks	For robust study summaries or as requested by the regulatory programme, provide any other specific information, e.g. the slope in probit units per log ₁₀ dose mortality curve if reported.

7.3.2.1.30. Mortality

Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. "Evidence of toxicity" describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality.

If the acute toxic class method was used, tabulate the number of moribund or dead animals for each dose step used.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.2.1.31. 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 NOAEL 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.

7.3.2.1.32. Body weight

Briefly describe whether animals gained or lost weight.

7.3.2.1.33. Gross pathology

Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.

7.3.2.1.34. Other findings

Include any further results using freetext template as appropriate. If applicable, briefly describe whether there were any treatment related differences in organ weights or histopathology and state if potential target organs were identified.

7.3.2.1.35. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.3.2.1.36. 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.

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.

7.3.2.1.37. 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.

Tabella E.377. Field Descriptions

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.
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.

7.3.2.1.38. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.3.2.1.39. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.3.2.1.40. Criteria used for interpretation of results

If the conclusions were based on hazard classification criteria, indicate the respective organisation. If no criteria are indicated in the report, enter "expert judgment", "no data" or "other: <describe>" as appropriate.

7.3.2.1.41. Conclusions

Enter any conclusions if applicable.

7.3.2.1.42. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.2.1.43. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.3. [7.2.2] Acute toxicity: inhalation

7.3.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.3.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.3.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.378. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.3.3.1.3. 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.

7.3.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.3.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.3.1.6. Test type

If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies.

If neither of these test types applies, either leave field empty or use "other:".

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.3.3.1.7. Limit test

Indicate if the experiment was a limit test.

7.3.3.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.379. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.3.3.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.3.3.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.3.3.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.3.3.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.380. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.3.3.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.3.3.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.3.3.1.15. 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.3.3.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.3.3.1.17. Sex

Select as appropriate.

7.3.3.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.3.3.1.19. Route of administration

Specify the route of administration by indicating in what physical form the test material was administered.

7.3.3.1.20. Type of inhalation exposure

Indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.3.3.1.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.3.3.1.22. 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 from the study report.

7.3.3.1.23. 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 variance 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".

7.3.3.1.24. Duration of exposure

Indicate total duration of exposure.

Tabella E.381. Field Descriptions

Duration (no label)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the recorded value as appropriate.

7.3.3.1.25. Concentrations

Include the nominal concentrations including the unit the test animals were exposed to, e.g. "5, 50, 500 and 2000 mg/l air". 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").

7.3.3.1.26. 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 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.3.1.27. Control animals

Indicate whether concurrent control group was used.

7.3.3.1.28. 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.

7.3.3.1.29. Statistics

Indicate the method of calculating the LC50 or other.

7.3.3.1.30. 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.

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.

7.3.3.1.31. Preliminary study (if fixed dose study)

In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.

7.3.3.1.32. 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 the test was conducted according to the fixed concentration procedure, include the discriminating dose, i.e. the highest out of the four fixed concentration levels to which the animals can be exposed without causing compound-related mortality (including human kills).

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".

Tabella E.382. Field Descriptions

Sex	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p>

	(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").
Unit of dose (no label)	Select from drop-down list.
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Exposure duration (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 (no label)	Select from drop-down list.
Remarks	For robust study summaries or as requested by the regulatory programme, provide any other specific information, e.g. the slope in probit units per log ₁₀ dose mortality curve if reported.

7.3.3.1.33. Mortality

Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. "Evidence of toxicity" describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality.

If the acute toxic class method was used, tabulate the number of moribund or dead animals for each concentration step used.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.3.1.34. 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 NOAEL 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.

7.3.3.1.35. Body weight

Briefly describe whether animals gained or lost weight.

7.3.3.1.36. Gross pathology

Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.

7.3.3.1.37. Other findings

Include any further results using freetext template as appropriate. If applicable, briefly describe whether there were any treatment related differences in organ weights or histopathology and state if potential target organs were identified.

7.3.3.1.38. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.3.3.1.39. 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.

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.

7.3.3.1.40. 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.

Tabella E.383. Field Descriptions

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.
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.

7.3.3.1.41. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.3.3.1.42. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this In the supplementary remarks field.

7.3.3.1.43. Criteria used for interpretation of results

If the conclusions were based on hazard classification criteria, indicate the respective organisation. If no criteria are indicated in the report, enter "expert judgment", "no data" or "other: <describe>" as appropriate.

7.3.3.1.44. Conclusions

Enter any conclusions if applicable.

7.3.3.1.45. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.3.1.46. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.4. [7.2.3] Acute toxicity: dermal

7.3.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.3.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.3.4.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.384. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.

Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.
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7.3.4.1.3. 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.

7.3.4.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.3.4.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.4.1.6. 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.

7.3.4.1.7. Limit test

Indicate if the experiment was a limit test.

7.3.4.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.385. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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7.3.4.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.3.4.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.3.4.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.3.4.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.386. Field Descriptions

Identifier	
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	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.3.4.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.3.4.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.3.4.1.15. 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.3.4.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.3.4.1.17. Sex

Select as appropriate.

7.3.4.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.3.4.1.19. Type of coverage

Select type of coverage used. For robust study summaries specify the area of application in field "Details on dermal exposure".

7.3.4.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.3.4.1.21. 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.

7.3.4.1.22. Duration of exposure

Indicate total duration of exposure in hours, e.g. "4 hrs".

7.3.4.1.23. Doses

Include the doses including unit administered to the test animals, "5, 50, 500 and 2000 mg/kg bw". As appropriate include notes in parentheses, e.g. "(male)".

For a robust study summary also indicate the analytical concentrations of the test substance in the vehicle in the results table (see field "Mortality").

7.3.4.1.24. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.4.1.25. Control animals

Indicate whether and what type of concurrent control groups were used or select "not required" if applicable.

7.3.4.1.26. 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.

7.3.4.1.27. Statistics

Indicate the method of calculating the LD50 or other.

7.3.4.1.28. 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.

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.

7.3.4.1.29. Preliminary study (if fixed dose study)

In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.

7.3.4.1.30. 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".

Tabella E.387. Field Descriptions

Sex	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select from drop-down list.
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p>

	(ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Remarks	For robust study summaries or as requested by the regulatory programme, provide any other specific information, e.g. the slope in probit units per log10 dose mortality curve if reported.

7.3.4.1.31. Mortality

Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. "Evidence of toxicity" describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.4.1.32. 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 NOAEL for clinical findings.

7.3.4.1.33. Body weight

Briefly describe whether animals gained or lost weight.

7.3.4.1.34. Gross pathology

Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.

7.3.4.1.35. Other findings

Include any further results using freetext template as appropriate. If applicable, briefly describe whether there were any treatment related differences in organ weights or histopathology and state if potential target organs were identified.

7.3.4.1.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.3.4.1.37. 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.

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.

7.3.4.1.38. 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.

Tabella E.388. Field Descriptions

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.
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.

7.3.4.1.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.3.4.1.40. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.3.4.1.41. Criteria used for interpretation of results

If the conclusions were based on hazard classification criteria, indicate the respective organisation. If no criteria are indicated in the report, enter "expert judgment", "no data" or "other: <describe>" as appropriate.

7.3.4.1.42. Conclusions

Enter any conclusions if applicable.

7.3.4.1.43. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.4.1.44. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.5. [7.2.4] Acute toxicity: other routes

7.3.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.3.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.3.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.389. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.3.5.1.3. 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.

7.3.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.3.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.3.5.1.6. Limit test

Indicate if the experiment was a limit test.

7.3.5.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.390. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.3.5.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.3.5.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.3.5.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.3.5.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.391. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.3.5.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.3.5.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.3.5.1.14. 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.3.5.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.3.5.1.16. Sex

Select as appropriate.

7.3.5.1.17. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.3.5.1.18. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.3.5.1.19. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.3.5.1.20. Details on exposure

Briefly describe details of exposure.

7.3.5.1.21. Doses

Include the doses including unit administered to the test animals, "5, 50, 500 and 2000 mg/kg bw". As appropriate include notes in parentheses, e.g. "(male)".

7.3.5.1.22. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.5.1.23. Control animals

Indicate whether concurrent control group was used.

7.3.5.1.24. 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.

7.3.5.1.25. Statistics

Indicate the method of calculating the LD50 or other.

7.3.5.1.26. 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.

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.

7.3.5.1.27. 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 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".

Tabella E.392. Field Descriptions

Sex	Select from drop-down list.
Endpoint	Select from drop-down list.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select from drop-down list.
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available.</p> <p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>

Remarks	For robust study summaries or as requested by the regulatory programme, provide any other specific information, e.g. the slope in probit units per log ₁₀ dose mortality curve if reported.
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7.3.5.1.28. Mortality

Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.5.1.29. 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 NOAEL for clinical findings.

7.3.5.1.30. Body weight

Briefly describe whether animals gained or lost weight.

7.3.5.1.31. Gross pathology

Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.

7.3.5.1.32. Other findings

Include any further results using freetext template as appropriate. If applicable, briefly describe whether there were any treatment related differences in organ weights or histopathology and state if potential target organs were identified.

7.3.5.1.33. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.3.5.1.34. 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.

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.

7.3.5.1.35. 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.

Tabella E.393. Field Descriptions

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.
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.

7.3.5.1.36. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.3.5.1.37. Conclusions

Enter any conclusions if applicable.

7.3.5.1.38. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.3.5.1.39. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.4. [7.3] Irritation / corrosion

7.4.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.4.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available

- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.4.1.2. Skin irritation / corrosion

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.4.1.3. Eye irritation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.4.1.4. Respiratory irritation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.4.1.5. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.4.1.6. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.4.2. [7.3.1] Skin irritation / corrosion

7.4.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.4.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.4.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.394. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.4.2.1.3. 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.

7.4.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.4.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.4.2.1.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.4.2.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.395. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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7.4.2.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.4.2.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.4.2.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.4.2.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.396. Field Descriptions

Identifier	
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	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.4.2.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.4.2.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.4.2.1.14. 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.

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: 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.4.2.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.4.2.1.16. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.4.2.1.17. Type of coverage

Select as appropriate. If not available from picklist, select "other" and specify.

7.4.2.1.18. Preparation of test site

Select as appropriate. If not available from picklist, select "other" and specify.

7.4.2.1.19. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any.

7.4.2.1.20. Amount/concentration applied

Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.

7.4.2.1.21. Duration of treatment / exposure

Indicate length of time test material was in contact with animal/cell including unit, e.g. "4 hours". Also indicate if different exposure time periods were applied in different tests of this study.

7.4.2.1.22. Observation period

Indicate length of observation period in days / hours.

7.4.2.1.23. Number of animals

Indicate number of animals used.

7.4.2.1.24. Control animals

Indicate whether and what type of concurrent control groups were used or select "not required" if applicable.

7.4.2.1.25. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.4.2.1.26. 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.

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.

7.4.2.1.27. Irritation / corrosion results

Indicate the overall irritation / corrosion results in terms of an Overall irritation score, Primary dermal irritation index or other (specify). Copy this block of fields as appropriate.

Tabella E.397. Field Descriptions

Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.
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Basis of irritation 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").
Time point	Indicate the time point(s) the score relates to, e.g. "24 h" or "1, 24, 48, 72 h" if score is equal for all scoring intervals or is the average score over all time points.
Score	Provide the numeric value or a range of values if reported so. Use 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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Scale (max. score) (Max. score)	Provide the numeric value of the total possible score depending on the scale used.
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.
Remarks	Any remarks related to the results recorded in this block of fields can be given.

7.4.2.1.28. 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").

Describe the method of calculation of maximum average score given in the results table.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.4.2.1.29. Other effects

Describe any other adverse local (e.g. defatting of skin) and systemic effects in addition to dermal irritation or corrosion.

7.4.2.1.30. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.4.2.1.31. 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.

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.

7.4.2.1.32. 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.

Tabella E.398. Field Descriptions

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.
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.

7.4.2.1.33. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.4.2.1.34. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.4.2.1.35. Criteria used for interpretation of results

If the conclusions were based on hazard classification criteria, indicate the respective organisation. If no criteria are indicated in the report, enter "expert judgment", "no data" or "other: <describe>" as appropriate.

7.4.2.1.36. Conclusions

Enter any conclusions if applicable.

7.4.2.1.37. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.4.2.1.38. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.4.3. [7.3.2] Eye irritation

7.4.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.4.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.4.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.399. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.4.3.1.3. 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.

7.4.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.4.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.4.3.1.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.4.3.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.400. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.4.3.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.4.3.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.4.3.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.4.3.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.401. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.4.3.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.4.3.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.4.3.1.14. 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.

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: 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 "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 to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.4.3.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.4.3.1.16. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.4.3.1.17. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any.

7.4.3.1.18. Amount/concentration applied

Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.

7.4.3.1.19. Duration of treatment / exposure

Indicate length of time test material was in contact with animal/cell including unit, e.g. "4 hours". Also indicate if different exposure time periods were applied in different tests of this study.

7.4.3.1.20. Observation period

Indicate length of observation period in days / hours.

7.4.3.1.21. Number of animals

Indicate number of animals used.

7.4.3.1.22. Control animals

Indicate whether and what type of concurrent control groups were used or select "not required" if applicable.

7.4.3.1.23. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.4.3.1.24. 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.

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.

7.4.3.1.25. Overall irritation / corrosion results

Indicate the overall irritation / corrosion results in terms of an either erythema score, edema score, overall irritation score, primary dermal irritation index or other (specify). Copy this block of fields for reporting several scores, e.g. means or for individual animals.

Tabella E.402. Field Descriptions

Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.
Basis of irritation 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").
Time point	Indicate the time point(s) the score relates to, e.g. "24 h" or "1, 24, 48, 72 h" if score is equal for all scoring intervals or is the average score over all time points.
Irritation score (no label)	Provide the numeric value or a range of values if reported so. Use 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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Scale (max. score) (Max. score)	Provide the numeric value of the total possible score depending on the scale used.
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.
Remarks	Any remarks related to the results recorded in this block of fields can be given.

7.4.3.1.26. 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").

Describe the method of calculation of maximum average score given in the results table.

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.4.3.1.27. Other effects

Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable.

7.4.3.1.28. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.4.3.1.29. 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.

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.

7.4.3.1.30. 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.

Tabella E.403. Field Descriptions

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.
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.

7.4.3.1.31. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.4.3.1.32. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.4.3.1.33. Criteria used for interpretation of results

If the conclusions were based on hazard classification criteria, indicate the respective organisation. If no criteria are indicated in the report, enter "expert judgment", "no data" or "other: <describe>" as appropriate.

7.4.3.1.34. Conclusions

Enter any conclusions if applicable.

7.4.3.1.35. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.4.3.1.36. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.5. [7.4] Sensitisation

7.5.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.5.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)
- Genetic toxicity:
In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.5.1.2. Skin sensitisation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.5.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.5.1.4. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability

score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.5.1.5. Respiratory sensitisation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.5.1.6. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.5.1.7. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.5.2. [7.4.1] Skin sensitisation

7.5.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.5.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.5.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.404. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.5.2.1.3. 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.

7.5.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.5.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.5.2.1.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables" and the results in field "Any other information on results incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.5.2.1.7. Type of study

Select type of study e.g. "Draize Test" as appropriate.

7.5.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.405. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	

	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.5.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.5.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.5.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.5.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.406. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.5.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.5.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.5.2.1.15. 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 "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-reference to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.5.2.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.5.2.1.17. Sex

Select as appropriate.

7.5.2.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.5.2.1.19. Route of induction exposure

Indicate the route of induction exposure.

7.5.2.1.20. Route of challenge exposure

Indicate the route of challenge exposure

7.5.2.1.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any.

7.5.2.1.22. Concentration

For each exposure phase (i.e. induction/challenge) provide the doses / concentrations of the test substance applied including unit (i.e. undiluted, %, % active substance, FCA, mg, g).

7.5.2.1.23. 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)".

7.5.2.1.24. Details on study design (Traditional tests)

For traditional 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

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

7.5.2.1.25. Challenge controls

Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application.

7.5.2.1.26. 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.

7.5.2.1.27. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If the vehicle used is not from the list a rationale must be provided in the supplementary remarks field.

7.5.2.1.28. 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.

7.5.2.1.29. No. of animals per dose

Provide number of animals per dose or range if different numbers were used, e.g. "4 per group (pooled lymph nodes)" or "5 per group (individual animals used)".

7.5.2.1.30. Details on study design (LLNA)

For LLNA, 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

- 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.

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. 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 6 an injection of 250 µl phosphate buffered saline (PBS) containing 20 µCi of 3H-methyl thymidine (3H-TdR) or 250 µl PBS containing 2 µCi of 125 I-iododeoxy-uridine (125IU) and 10⁻⁵ M fluorodeoxy-uridine was made into the tail vein of each experimental mouse. Five hours later, the draining Auricular lymph node of each ear was excised into PBS. A single cell suspension of lymph node cells was prepared from each mouse. (describe method of cell suspension). Cells were precipitated with 5% trichloroacetic acid at 4 °C for 18 hours.

7.5.2.1.31. Positive control substance(s)

Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate. Copy this field if more than one substance was used.

7.5.2.1.32. Statistics

Provide the statistical procedures employed (e.g., linear regression analysis to assess dose-response trends; Dunnett's test to make pairwise comparisons).

7.5.2.1.33. 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.

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.

7.5.2.1.34. Positive control results

Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.

7.5.2.1.35. Results of test (except LLNA)

Record the results of traditional 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.

Tabella E.407. Field Descriptions

Reading	Select from drop-down list.
Hours after challenge	Enter numeric value.
Group	Select from drop-down list.
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".
Number of animals with positive reactions (No. with + reactions)	Enter numeric value.
Total number of animals in group (Total no. in group)	Enter numeric value.
Clinical observations	Briefly describe relevant clinical observations.

7.5.2.1.36. Disintegrations per minute (DPM)

Briefly describe the results of DPM measurements. Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean DPMs compared to control. Indicate whether results are from the individual animals or pooled. As appropriate include table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.5.2.1.37. Stimulation index

Briefly describe the calculated SI and EC3. Calculation of $\mu\text{g}/\text{cm}^2$ dose applied. As appropriate include table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.5.2.1.38. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.5.2.1.39. 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.

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.

7.5.2.1.40. 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.

Tabella E.408. Field Descriptions

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.
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.

7.5.2.1.41. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.5.2.1.42. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.5.2.1.43. Conclusions

Enter any conclusions if applicable.

7.5.2.1.44. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.5.2.1.45. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.5.3. [7.4.2] Respiratory sensitisation

7.5.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.5.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.5.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.409. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.5.3.1.3. 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.

7.5.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.5.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.5.3.1.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables" and the results in field "Any other information on results incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.5.3.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.410. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.5.3.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.5.3.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.5.3.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.5.3.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.411. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.5.3.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.5.3.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.5.3.1.14. 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 "Exposure related observations", particularly subsection "Sensitisation data".

It can be useful to document, in section "Respiratory sensitisation", that human data are provided by creating a record and referring to the human data in field "Cross-reference to same study". This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record.

7.5.3.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.5.3.1.16. Sex

Select as appropriate.

7.5.3.1.17. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.5.3.1.18. Route of induction exposure

Indicate the route of induction exposure. Remarks can be entered in the supplementary remarks field.

7.5.3.1.19. Route of challenge exposure

Indicate the route of challenge exposure. Remarks can be entered in the supplementary remarks field.

7.5.3.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any.

7.5.3.1.21. Concentration

For each exposure phase (i.e. induction/challenge) provide the doses / concentrations of the test substance applied including unit.

7.5.3.1.22. No. of animals per dose

Provide number of animals per dose or state if different numbers were used, e.g. "3 (controls), 5 (in test groups)".

7.5.3.1.23. Details on study design

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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.5.3.1.24. Challenge controls

Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application.

7.5.3.1.25. Positive control substance(s)

Indicate the positive control substance(s) used (i.e. substances known to cause respiratory sensitisation in animals) and give additional remarks in supplementary field as appropriate. If not listed, use "other:" and specify or select "none" or "no data" as applicable.

Copy this field if more than one substance was used.

7.5.3.1.26. Negative control substance(s)

Indicate the negative control substance(s) used (i.e. substances known to lack the ability to cause respiratory sensitisation in animals) and give additional remarks in supplementary field as appropriate. If not listed, use "other:" and specify or select "none" or "no data" as applicable.

Copy this field if more than one substance was used.

7.5.3.1.27. 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.

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.

7.5.3.1.28. Results

Report the results of the test(s) performed. Include an interpretation of the results in field "Conclusions".

7.5.3.1.29. Positive control results

Discuss the positive control results and demonstrate that the laboratory has the capability to identify substances known to cause respiratory sensitisation in animals.

7.5.3.1.30. Negative control results

Discuss the negative control results and demonstrate that the laboratory has the capability to identify substances known to lack the ability to cause respiratory sensitisation in animals.

7.5.3.1.31. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.5.3.1.32. 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.

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.

7.5.3.1.33. 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.

Tabella E.412. Field Descriptions

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.
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.

7.5.3.1.34. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.5.3.1.35. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter.

Note that a classification in the strict sense is normally not based on an individual study, but includes a weight of evidence evaluation of all relevant data. However, if a single study is used for a classification, you can indicate this in the supplementary remarks field.

7.5.3.1.36. Conclusions

Enter any conclusions if applicable.

7.5.3.1.37. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.5.3.1.38. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6. [7.5] Repeated dose toxicity

7.6.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.6.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available

- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.6.1.2. Repeated dose toxicity: oral

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.6.1.3. Repeated dose toxicity: dermal

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.6.1.4. Repeated dose toxicity: inhalation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.

- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.6.1.5. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.6.1.6. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.6.2. [7.5.1] Repeated dose toxicity: oral

7.6.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.6.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.6.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.413. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.6.2.1.3. 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.

7.6.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.6.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.2.1.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.6.2.1.7. Limit test

Indicate if the experiment was a limit test.

7.6.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.414. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.6.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.6.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.6.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.6.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.415. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.6.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.6.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.6.2.1.15. Species

Select name of species from respective sub-picklist, i.e. "Common rodent species" (for rat and mouse), "Common non-rodent species" (for dog if applicable) or "Other species" (for any other).

7.6.2.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.6.2.1.17. Sex

Select as appropriate.

7.6.2.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.6.2.1.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.6.2.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.6.2.1.21. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.6.2.1.23. Details on analytical verification of doses or concentrations

For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.

If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.

If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field "Rationale for reliability incl. deficiencies".

It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.

7.6.2.1.24. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "104 weeks" or "90 days".

7.6.2.1.25. 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.

7.6.2.1.26. Doses/concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.416. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. "0, 112, 220, 523 mg/kg bw/day (m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text.
Basis	Indicate whether the doses or concentrations recorded are based on nominal or actually ingested values.

7.6.2.1.27. 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. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.28. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.6.2.1.29. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.30. Positive control

Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.

7.6.2.1.31. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.33. Other examinations

Describe any other examinations.

7.6.2.1.34. 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.

7.6.2.1.35. 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.

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.

7.6.2.1.36. Effect levels

Record the available NO(A)EL(s) and/or LO(A)EL(s).

Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.

Tabella E.417. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEL or LOAEL. If adverse effects were observed at the highest dose tested, select "no NOAEL identified". 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.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.

Basis for effect level / Remarks	<p>Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Delete any elements in the predefined freetext that do not apply.</p> <p>This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.</p>
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7.6.2.1.37. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.38. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.39. Food consumption and compound intake (if feeding study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.40. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.41. Water consumption and compound intake (if drinking water study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.6.2.1.42. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.43. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.44. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.45. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.46. Neurobehaviour

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".

7.6.2.1.47. Organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.48. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.49. Histopathology: non-neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.2.1.50. Histopathology: neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".

7.6.2.1.51. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.

- WATER CONSUMPTION AND COMPOUND INTAKE (if drinking water study): Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.
- NEUROBEHAVIOUR: It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".
- HISTOPATHOLOGY: NEOPLASTIC (if applicable): In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".
- HISTORICAL CONTROL DATA (if applicable): Provide data and indicate dates study was conducted if useful for the interpretation of the results.

Reference such information in the fields for bibliographic references.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.6.2.1.52. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.6.2.1.53. 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.

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.

7.6.2.1.54. 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.

Tabella E.418. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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7.6.2.1.55. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.6.2.1.56. Conclusions

Enter any conclusions if applicable.

7.6.2.1.57. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.2.1.58. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.3. [7.5.2] Repeated dose toxicity: dermal

7.6.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.6.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.6.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.419. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.6.3.1.3. 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.

7.6.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.6.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.3.1.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.6.3.1.7. Limit test

Indicate if the experiment was a limit test.

7.6.3.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.420. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.6.3.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.6.3.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.6.3.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.6.3.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.421. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.6.3.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.6.3.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.6.3.1.15. Species

Select name of species from respective sub-picklist, i.e. "Common species" (for mouse, rat, rabbit or guinea pig) or "Other species" (for any other).

7.6.3.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.6.3.1.17. Sex

Select as appropriate.

7.6.3.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.6.3.1.19. 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".

7.6.3.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.6.3.1.21. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.6.3.1.23. Details on analytical verification of doses or concentrations

For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.

If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.

If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field "Rationale for reliability incl. deficiencies".

It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.

7.6.3.1.24. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "104 weeks" or "90 days".

7.6.3.1.25. 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.

7.6.3.1.26. Doses/concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.422. Field Descriptions

Doses / concentrations (no label)	Indicate the dose levels as determined on the basis of quantity per unit area of exposed skin (expressed as mg/cm ² per day) and/or on the basis of quantity per unit of body weight (mg/kg bw/day), e.g. "0, 112, 220, 523 mg/kg bw/day
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	(m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text.
Basis	Indicate whether the doses recorded are based on nominal or analytical values.

7.6.3.1.27. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.28. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.6.3.1.29. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.30. Positive control

Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.

7.6.3.1.31. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.32. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.33. Other examinations

Describe any other examinations.

7.6.3.1.34. 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.

7.6.3.1.35. 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.

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.

7.6.3.1.36. Effect levels

Record the available NO(A)EL(s) and/or LO(A)EL(s).

Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.

Tabella E.423. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEL or LOAEL. If adverse effects were observed at the highest dose tested, select "no NOAEL identified". If a
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	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.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.
Basis for effect level / Remarks	<p>Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Delete any elements in the predefined freetext that do not apply.</p> <p>This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.</p>

7.6.3.1.37. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.38. Dermal irritation

Indicate whether any treatment-related effects were observed. If "no" is entered, you may include any remarks in the associated supplementary remarks field, e.g. for explaining any negligible effects. If "yes" is selected, describe the effects by dose in the supplementary remarks field. Note when signs were first observed and if they were reversible. Describe the specific score used for scoring irritation.

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).

7.6.3.1.39. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.40. Food consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.41. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.42. Water consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.6.3.1.43. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.44. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.45. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.46. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.47. Neurobehaviour

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".

7.6.3.1.48. Organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.49. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.50. Histopathology: non-neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.3.1.51. Histopathology: neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".

7.6.3.1.52. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.
- DERMAL IRRITATION: Note when signs were first observed and if they were reversible. Describe the specific score used for scoring irritation.
- WATER CONSUMPTION: Water consumption may not be specifically requested under the respective test guideline.

- NEUROBEHAVIOUR: It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".
- HISTOPATHOLOGY: NEOPLASTIC (if applicable): In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".
- HISTORICAL CONTROL DATA (if applicable): Provide data and indicate dates study was conducted if useful for the interpretation of the results.

Reference such information in the fields for bibliographic references.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.6.3.1.53. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.6.3.1.54. 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.

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.

7.6.3.1.55. 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.

Tabella E.424. Field Descriptions

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.
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.

7.6.3.1.56. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.6.3.1.57. Conclusions

Enter any conclusions if applicable.

7.6.3.1.58. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.3.1.59. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.4. [7.5.3] Repeated dose toxicity: inhalation

7.6.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.6.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.6.4.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.425. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.6.4.1.3. 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.

7.6.4.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.6.4.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.4.1.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.6.4.1.7. Limit test

Indicate if the experiment was a limit test.

7.6.4.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.426. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.6.4.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.6.4.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.6.4.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.6.4.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.427. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.6.4.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.6.4.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.6.4.1.15. Species

Select name of species from respective sub-picklist, i.e. "Common rodent species" (for rat and mouse), "Common non-rodent species" (for dog if applicable) or "Other species" (for any other).

7.6.4.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.6.4.1.17. Sex

Select as appropriate.

7.6.4.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.6.4.1.19. Route of administration

Specify the route of administration by indicating in what physical form the test material was administered.

7.6.4.1.20. Type of inhalation exposure

Indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.6.4.1.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.6.4.1.22. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.23. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.6.4.1.24. Details on analytical verification of doses or concentrations

For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.

If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.

If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field "Rationale for reliability incl. deficiencies".

It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.

7.6.4.1.25. Duration of treatment / exposure

Indicate total duration of exposure in days, weeks or months, e.g. "104 weeks" or "90 days".

7.6.4.1.26. Frequency of treatment

Indicate the frequency of the administration of doses to the test animals (e.g., "8 hours/day, 7 days/week"). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.

7.6.4.1.27. Doses/concentrations

Indicate the concentration levels applied including unit and the basis of quantity used. In parentheses note if concentrations were corrected for % active ingredient if applicable. Copy this block of fields if the concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.428. Field Descriptions

Doses / concentrations (no label)	Specify the test atmosphere concentrations including unit, e.g. "0, 1.2, 2.1, 5.3 mg/l air". You may enter explanatory text.
Basis	Indicate whether the concentrations recorded are based on nominal or analytical values.

7.6.4.1.28. MMAD / GSD

Specify the particle size distribution in terms of mass median aerodynamic diameter in μm (MMAD) and geometric standard deviation (GSD) from the mean.

7.6.4.1.29. No. of animals per sex per dose

Enter value or specify according to test group if different number of animals per group, e.g. "10 in each test group of main study; 10 f and 5 m in interim sacrifice group". Also specify number of animals in recovery group if applicable.

For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.30. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.6.4.1.31. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.32. Positive control

Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.

7.6.4.1.33. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.34. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.35. Other examinations

Describe any other examinations.

7.6.4.1.36. 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.

7.6.4.1.37. 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.

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.

7.6.4.1.38. Effect levels

Record the available NO(A)EL(s) and/or LO(A)EL(s).

Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.

Tabella E.429. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEC or LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEC identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" 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.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Delete any elements in the predefined freetext that do not apply. This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEC = highest conc. tested" if applicable.

7.6.4.1.39. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.40. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.41. Food consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.42. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.43. Water consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.6.4.1.44. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.45. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.46. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.47. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.48. Neurobehaviour

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".

7.6.4.1.49. Organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.50. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.51. Histopathology: non-neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.4.1.52. Histopathology: neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".

7.6.4.1.53. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.
- WATER CONSUMPTION: Water consumption may not be specifically requested under the respective test guideline.
- NEUROBEHAVIOUR: It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".
- HISTOPATHOLOGY: NEOPLASTIC (if applicable): In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".
- HISTORICAL CONTROL DATA (if applicable): Provide data and indicate dates study was conducted if useful for the interpretation of the results.

Reference such information in the fields for bibliographic references.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.6.4.1.54. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.6.4.1.55. 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.

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.

7.6.4.1.56. 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.

Tabella E.430. Field Descriptions

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.
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.

7.6.4.1.57. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.6.4.1.58. Conclusions

Enter any conclusions if applicable.

7.6.4.1.59. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.4.1.60. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.5. [7.5.4] Repeated dose toxicity: other routes

7.6.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.6.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.6.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.431. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.6.5.1.3. 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.

7.6.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.6.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.6.5.1.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.6.5.1.7. Limit test

Indicate if the experiment was a limit test.

7.6.5.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.432. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.6.5.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.6.5.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.6.5.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.6.5.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.433. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.6.5.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.6.5.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.6.5.1.15. Species

Select name of species. If not available from picklist, select "other" and specify.

7.6.5.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.6.5.1.17. Sex

Select as appropriate.

7.6.5.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.6.5.1.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.6.5.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.6.5.1.21. Details on exposure

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.6.5.1.23. Duration of treatment / exposure

Indicate total duration of exposure in days, weeks or months, e.g. "104 weeks" or "90 days".

7.6.5.1.24. Frequency of treatment

Indicate the frequency of the administration of doses to the test animals (e.g., "8 hours/day, 7 days/week"). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.

7.6.5.1.25. Doses / concentrations

Indicate the doses or concentrations including unit applied to the test animals, e.g. "0, 112, 220, 523 mg/kg bw/day (m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text. Indicate whether the doses recorded are based on nominal or analytical values.

7.6.5.1.26. No. of animals per sex per dose

Enter value or specify according to test group if different number of animals per group, e.g. "10 in each test group of main study; 10 f and 5 m in interim sacrifice group". Also specify number of animals in recovery group if applicable.

For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.27. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.6.5.1.28. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.29. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.30. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.31. Other examinations

Describe any other examinations.

7.6.5.1.32. 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.

7.6.5.1.33. 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.

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.

7.6.5.1.34. Effect levels

Record the available NO(A)EL(s) and/or LO(A)EL(s).

Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.

Tabella E.434. Field Descriptions

Endpoint	Select type of endpoint, e.g. NOAEC or NOAEL. If adverse effects were observed at the highest dose tested, select "no NOAEC identified" or "no NOAEL identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" and specify in the related
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	text field). If the critical effects at a specific dose or concentration level are reported only, select "dose. level:" or "conc. level:" and specify.
Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.
Basis for effect level / Remarks	<p>Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Delete any elements in the predefined freetext that do not apply.</p> <p>This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.</p>

7.6.5.1.35. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.36. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.37. Food consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.38. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.39. Water consumption

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.6.5.1.40. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.41. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.42. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.43. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.44. Neurobehaviour

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".

7.6.5.1.45. Organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.46. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.47. Histopathology: non-neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.6.5.1.48. Histopathology: neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".

7.6.5.1.49. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.
- WATER CONSUMPTION: Water consumption may not be specifically requested under the respective test guideline.
- NEUROBEHAVIOUR: It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".
- HISTOPATHOLOGY: NEOPLASTIC (if applicable): In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".
- HISTORICAL CONTROL DATA (if applicable): Provide data and indicate dates study was conducted if useful for the interpretation of the results.

Reference such information in the fields for bibliographic references.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.6.5.1.50. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.6.5.1.51. 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.

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.

7.6.5.1.52. 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.

Tabella E.435. Field Descriptions

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.
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.

7.6.5.1.53. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.6.5.1.54. Conclusions

Enter any conclusions if applicable.

7.6.5.1.55. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.6.5.1.56. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.7. [7.6] Genetic toxicity

7.7.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.7.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)

- Oxidation reduction potential: no data available
- Phototransformation in air: $T_{1/2} = 9.32 \times 10^{-2}$ yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.7.1.2. Genetic toxicity

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.

- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.7.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.7.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.7.2. [7.6.1] Genetic toxicity in vitro

7.7.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.7.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.7.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.436. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.7.2.1.3. 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.

7.7.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.7.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.7.2.1.6. Type of genotoxicity

Indicate the type of genotoxicity addressed, i.e. gene mutation, chromosome aberration, DNA damage and/or repair or genome mutation.

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.7.2.1.7. Type of study

Indicate the type of study.

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons. Indicate the type of study.

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.7.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.437. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.7.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.7.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.7.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.7.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.438. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.7.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.7.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.7.2.1.15. Target gene

Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system.

7.7.2.1.16. 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.

Tabella E.439. Field Descriptions

Species/strain	Select as appropriate. If not available from picklist, select "other" and specify.
Cell culture details (if applicable) (Details on mammalian cell lines (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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.
Additional strain 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.
Metabolic activation	Indicate whether metabolic activation was applied or not. Select "not applicable" for mammalian cell lines when no exogenous metabolic system is required.
Metabolic activation system	For robust study summaries, specify metabolic activation system, if any. Use predefined table to indicate substance used for induction, species and organ from which the activation system was prepared. 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"). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.2.1.17. Test concentrations

Indicate the test concentrations without and with metabolic activation.

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").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.2.1.18. Vehicle

Indicate whether and which vehicle(s)/solvent(s) was/were used or state "none" or "no data" as applicable. Indicate if different substances were used for tests with and without metabolic activation.

Provide the volume of vehicle/solvent in the medium (e.g. "DMSO (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.

Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.

7.7.2.1.19. Controls

Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as necessary, particularly if controls or different substances were used for tests with and without metabolic activation or for different tester strains. If necessary, indicate so in the supplementary remarks field. or in subfield "Remarks".

Tabella E.440. Field Descriptions

Negative controls	Indicate whether 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. Any explanations can be given in the supplementary remarks field.
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.
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) in the supplementary remarks field.
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 following field.

Positive control substance	<p>If applicable, indicate what substance was used as positive control. If several substances were used, repeat this block of fields accordingly. If different substances were used for tests with and without metabolic activation or for different tester strains, include a remark in subfield "Remarks".</p> <p>If other than the reference substance(s) specified in the test guidelines was/were used include a brief justification in the supplementary remarks field.</p> <p>Note that the list of substances provided is not exhaustive.</p>
Remarks	Enter any remarks related to the recorded controls as appropriate.

7.7.2.1.20. Details on test system and 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.2.1.21. Evaluation criteria

Describe the evaluation criteria used in the study to judge if a substance is positive.

7.7.2.1.22. 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.

7.7.2.1.23. 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.

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.

7.7.2.1.24. 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 detailed tables on the genotoxicity and cytotoxicity results and refer to respective table no. (use predefined table if any).

Tabella E.441. Field Descriptions

Species/strain	Indicate the species/strain or cell type tested. For the bacterial reverse mutation assay, "S. typhimurium TA 1535, TA 1537, TA 98 and TA 100" can be selected if all these strains were tested. Otherwise multiply this block of fields for each tester strain.
Metabolic activation	Indicate whether metabolic activation was applied or not.
Test system	Indicate "all strains/cell types tested" or select "strain/cell type: " and specify in the supplementary remarks field.
Genotoxicity	Indicate result of the test conducted with the tester strain(s) and the metabolic activation system specified. If positive or ambiguous, include concentration(s) in the supplementary remarks field or representative table. 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"). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.
Cytotoxicity	Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the supplementary remarks field or refer to results table. 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"). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.
Vehicle controls valid	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.
Negative controls valid	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.
Positive controls valid	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.

7.7.2.1.25. 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.

7.7.2.1.26. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.7.2.1.27. 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.

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.

7.7.2.1.28. 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.

Tabella E.442. Field Descriptions

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.
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.

7.7.2.1.29. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.7.2.1.30. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter or for any other explanations.

Copy this field for differentiating between results with / without metabolic activation.

7.7.2.1.31. Conclusions

Enter any conclusions if applicable.

7.7.2.1.32. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.2.1.33. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.7.3. [7.6.2] Genetic toxicity in vivo

7.7.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.7.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.7.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.443. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.7.3.1.3. 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.

7.7.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.7.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.7.3.1.6. Type of genotoxicity

Indicate the type of genotoxicity addressed, i.e. gene mutation, chromosome aberration, DNA damage and/or repair or genome mutation.

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.7.3.1.7. Type of study

Indicate the type of study.

Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.7.3.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.444. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.7.3.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.7.3.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.7.3.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.7.3.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.445. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.7.3.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.7.3.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.7.3.1.15. Species

Select name of species. If not available from picklist, select "other" and specify.

7.7.3.1.16. Strain

Select as appropriate. If not available from picklist, select "other" and specify.

7.7.3.1.17. Sex

Select as appropriate.

7.7.3.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.

- 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).

7.7.3.1.19. 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.

7.7.3.1.20. Vehicle(s)

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.

7.7.3.1.21. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.3.1.22. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "5 days" or "10 weeks".

7.7.3.1.23. 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").

7.7.3.1.24. Post exposure period

Indicate observation period (in days, weeks, months) after last exposure to the test material.

7.7.3.1.25. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.446. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day. You may enter explanatory text, e.g., indicate if the study was a limit test..
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.7.3.1.26. 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 table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.3.1.27. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.7.3.1.28. 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.

7.7.3.1.29. 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").

7.7.3.1.30. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.3.1.31. Evaluation criteria

Describe the evaluation criteria used in the study to judge if a substance is positive.

7.7.3.1.32. 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.

7.7.3.1.33. 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.

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.

7.7.3.1.34. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Tabella E.447. Field Descriptions

Sex	Select from drop-down list.
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.
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".
Vehicle controls valid	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.
Negative controls valid	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.
Positive controls valid	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.

7.7.3.1.35. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.3.1.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.7.3.1.37. 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.

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.

7.7.3.1.38. 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.

Tabella E.448. Field Descriptions

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.
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.

7.7.3.1.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.7.3.1.40. Interpretation of results

Indicate overall interpretation of test results as given in the study report or as concluded by the submitter. Use supplementary remarks field for indicating if conclusions originally reported were changed by submitter or for any other explanations.

7.7.3.1.41. Conclusions

Enter any conclusions if applicable.

7.7.3.1.42. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.7.3.1.43. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.8. [7.7] Carcinogenicity

7.8.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.8.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used,

test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.8.1.2. Carcinogenicity: oral

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.8.1.3. Carcinogenicity: dermal

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.8.1.4. Carcinogenicity: inhalation

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.8.1.5. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.8.1.6. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.8.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.8.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.8.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.449. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.8.2.3. 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.

7.8.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.8.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.8.2.6. Limit test

Indicate if the experiment was a limit test.

7.8.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.450. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.8.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.8.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.8.2.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.8.2.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.451. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.8.2.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.8.2.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.8.2.14. Species

Select name of species.

7.8.2.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.8.2.16. Sex

Select as appropriate.

7.8.2.17. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.8.2.18. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.8.2.19. Type of inhalation exposure (if applicable)

If route of administration is "inhalation", indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.8.2.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.8.2.21. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.8.2.23. 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.

7.8.2.24. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "104 weeks" or "18 months".

7.8.2.25. 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.

7.8.2.26. Post exposure period

Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.

7.8.2.27. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.452. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day. You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.8.2.28. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.29. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.8.2.30. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.31. Positive control

Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.

7.8.2.32. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.33. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.34. Other examinations

Describe any other examinations.

7.8.2.35. 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.

7.8.2.36. 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.

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.

7.8.2.37. Effect levels

Record effect levels, based on different endpoints and effect types (i.e. toxicity, carcinogenicity) and/or separated for each sex. Copy this block of fields as appropriate. Note that some legislation may not allow to give a NOAEL or NOAEC for carcinogenicity. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

In case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on systemic, i.e. non- neoplastic effects in the corresponding section for Repeated dose toxicity. If so, include a reference to that record in field "Cross-reference to same study".

Tabella E.453. Field Descriptions

Endpoint	Select type of endpoint, e.g. T25 or NOAEL. If adverse effects were observed at the highest dose tested, select "no NOAEC identified" or "no NOAEL identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" 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.
Effect type	Indicate whether data refer to carcinogenic or toxic effects.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Delete any elements in the predefined freetext that do not apply. This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.

7.8.2.38. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.39. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.40. Food consumption and compound intake (if feeding study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.41. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.42. Water consumption and compound intake (if drinking water study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.8.2.43. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.44. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.45. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.46. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.47. Neurobehaviour

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".

7.8.2.48. Organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.49. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.50. Histopathology: non-neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.8.2.51. Histopathology: neoplastic

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

In the case of a combined repeated dose and carcinogenicity study, it may be appropriate to record the data on neoplastic effects in the chapter on Carcinogenicity. If so, include a reference to that record in field "Cross-reference to same study".

7.8.2.52. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.

- WATER CONSUMPTION AND COMPOUND INTAKE (if drinking water study): Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.
- NEUROBEHAVIOUR: It may be appropriate to record the data on neurobehavioural effects in the chapter on Neurotoxicity. If so, refer to that study in field "Cross-reference to same study".
- HISTORICAL CONTROL DATA (if applicable): Provide data and indicate dates study was conducted if useful for the interpretation of the results.

Reference such information in the fields for bibliographic references.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.8.2.53. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.8.2.54. 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.

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.

7.8.2.55. 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.

Tabella E.454. Field Descriptions

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.
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.

7.8.2.56. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.8.2.57. Relevance of carcinogenic effects / potential

Discuss carcinogenic effects / potential, i.e. state if there was (not) a treatment related increase in tumour incidence as compared to controls and specify tumour type if applicable. Indicate if dosing was not considered adequate. Discuss weight of evidence with respect to relevance of tumours observed for human health.

Discuss conclusions given in supporting documentation.

7.8.2.58. Conclusions

Enter any conclusions if applicable.

7.8.2.59. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.8.2.60. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9. [7.8] Toxicity to reproduction

7.9.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.9.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.9.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.9.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.9.1.4. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:
LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)
LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)
- Acute toxicity:
Dermal: LD50: > 2,000 mg/kg for rat (limit test)
- Genetic toxicity:
In vitro:
Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.9.1.5. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.9.1.6. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.9.1.7. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203)

LC50 (48h) = 3.2 mg/l for Oryzias latipes (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): S. typhimurium TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.9.1.8. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.9.1.9. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.9.2. [7.8.1] Toxicity to reproduction

7.9.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.9.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.9.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.455. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.9.2.1.3. 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.

7.9.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.9.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9.2.1.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.9.2.1.7. Limit test

Indicate if the experiment was a limit test.

7.9.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.456. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.9.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.9.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.9.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.9.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.457. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.9.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.9.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.9.2.1.15. Species

Select name of species.

7.9.2.1.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.9.2.1.17. Sex

Select as appropriate.

7.9.2.1.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.9.2.1.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.9.2.1.20. Type of inhalation exposure (if applicable)

If route of administration is "inhalation", indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.9.2.1.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.9.2.1.22. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.23. Details on mating procedure

Briefly describe the mating procedure.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.24. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.9.2.1.25. 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.

7.9.2.1.26. Duration of treatment / exposure

Indicate duration of treatment or exposure (with unit) for each reproductive phase and generation,

e.g.

(P) Males: [...] days/weeks before mating.

(P) Females: [...] days/weeks before mating, [...] days/weeks during mating, [...] days/weeks during resulting pregnancies, [...] days/weeks through weaning of their F1 offspring.

(F1) Males: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation.

(F1) Females: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation.

7.9.2.1.27. 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.

7.9.2.1.28. Details on study schedule

Briefly describe the study schedule as far as not indicated under "Duration of treatment / 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

If necessary expand the information with corresponding data on F2 animals if applicable.

7.9.2.1.29. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.458. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day (P and F1, m/f)" or "0, 112, 220, 523 mg/kg bw/day (P, m); 0, 87, 198, 477 mg/kg bw/day (P, f)". You may enter explanatory text.
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Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.
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7.9.2.1.30. No. of animals per sex per dose

Indicate number of animals used per dose group, e.g. [#] (P) males caged with [#] (P) females; [#] (F1) males, [#] (F1) females.

For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field "Any other information on results incl. tables". Upload predefined 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.31. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.9.2.1.32. Further details on study design

Include any details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.33. Positive control

Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.

7.9.2.1.34. Parental animals: Observations and examinations

Indicate which clinical examinations were performed in the parental animals and the time schedule for those examinations. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined 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 study is a combined repeated dose toxicity / reproduction toxicity study or includes a developmental neurotoxicity part, include a note in field "Cross-reference to same study" and describe these study parts separately in the respective data point entry form(s), i.e. "Repeated dose toxicity (route x)" or "Neurotoxicity".

Use freetext template 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.35. Estrous cyclicity (Parental animals)

Indicate whether and how [e.g., vaginal smear] and for how long [x cycles or x weeks] the estrous cyclicity was determined.

7.9.2.1.36. Sperm parameters (Parental animals)

Indicate which sperm parameters were examined. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all.

7.9.2.1.37. Litter observations

Indicate which litter observations were made. State if any examination was not performed and with what generation as applicable. Also indicate the dose groups that were examined if not all.

In parentheses, include the time of observation (lactation day), e.g. (Day 0). As an alternative option, 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.38. Postmortem examinations (Parental animals)

Indicate when the surviving parental males/females were sacrificed and the postmortem examinations performed. Use freetext template and delete/add elements as appropriate. As an alternative option, include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined 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").

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.39. Postmortem examinations (Offspring)

Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined if not all. Use freetext template and delete/add elements as appropriate. As an alternative option or in addition, include a table and refer to respective table no. (use predefined table if any).

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.40. Statistics

List parameters that were analyzed by which test methods. Indicate whether these are appropriate.

Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.

7.9.2.1.41. Reproductive indices

Describe which reproductive indices were calculated from breeding and parturition records of animals in the study. Include formulas or descriptions as provided in the study report.

7.9.2.1.42. Offspring viability indices

Describe which viability indices were calculated from lactation records of litters in the study. Include formulas or descriptions as provided in the study report.

7.9.2.1.43. 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.

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.

7.9.2.1.44. Effect levels

Record effect levels, based on different endpoints and/or separated for each generation and/or sex. Copy this block of fields as appropriate.

Tabella E.459. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEC or LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEC identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" 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.
Generation	Select the generation (e.g. "P") the effect level refers to.
Sex	Select from drop-down list.

Effect level	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Basis for effect level / Remarks	<p>Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement" or "fertility index". Delete any elements in the predefined freetext that do not apply.</p> <p>This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.</p>

7.9.2.1.45. Clinical signs (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.46. Body weight and food consumption (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.47. Test substance intake (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.48. Reproductive function: estrous cycle (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.49. Reproductive function: sperm measures (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.9.2.1.50. Reproductive performance (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.51. Organ weights (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.52. Gross pathology (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.53. Histopathology (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results (parental animals)", describe the effects for each parental generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.54. Details on results (parental animals)

Describe the effects for each parental generation by dose and sex for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

Explanations:

- CLINICAL SIGNS AND MORTALITY (PARENTAL ANIMALS): Describe gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities indicate the cause of death.
- BODY WEIGHT AND FOOD CONSUMPTION (PARENTAL ANIMALS): Include selected group mean body weights and food consumption values for pregnant or nursing dams as summarised in the report. Present/discuss findings during gestation and lactation for each generation. If data are tabulated, split data into more than one table as appropriate.
- TEST SUBSTANCE INTAKE (PARENTAL ANIMALS): Include the doses expressed as mean daily mg test substance/kg bw during the pre-mating period (specify the # of weeks) based on food consumption (or drinking water consumption if drinking water study), body weight and dietary analyses results (if any). Indicate whether the values for the [P or F1] generation are considered to be representative of the test substance intake for the entire study. Likewise, indicate the test substance intake during pregnancy and during the lactation periods.
- REPRODUCTIVE FUNCTION: ESTROUS CYCLE (PARENTAL ANIMALS): Summarise, for each generation, any biologically relevant effects on the estrous cycle, i.e. length and periodicity, based on the results from the evaluation of vaginal smears (describe).
- REPRODUCTIVE FUNCTION: SPERM MEASURES (PARENTAL ANIMALS): Summarise, for each generation, any biologically relevant effects on sperm parameters, i.e. testis weight, epididymis weight, daily sperm production, sperm count in testes, sperm count in epididymides, enumeration of cauda epididymal sperm reserve, sperm motility, sperm morphology, other.
- REPRODUCTIVE PERFORMANCE (PARENTAL ANIMALS): Summarise any biologically relevant effects on reproductive performance for each generation and sex. Any table included should be based on report content and include any calculated reproductive indices.
- ORGAN WEIGHTS (PARENTAL ANIMALS): Give absolute and relative organ weight changes as appropriate; relate to any histological findings.

- GROSS PATHOLOGY (PARENTAL ANIMALS): State treatment-related findings and relate with other findings as appropriate.
- HISTOPATHOLOGY (PARENTAL ANIMALS): State treatment-related findings and relate with other findings as appropriate.
- OTHER FINDINGS (PARENTAL ANIMALS): Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.9.2.1.55. Viability (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.56. Clinical signs (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.57. Body weight (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.58. Sexual maturation (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.59. Organ weights (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.60. Gross pathology (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.61. Histopathology (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results (offspring)", describe the effects for each generation by dose and sex (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.2.1.62. Details on results (offspring)

Describe the effects for each generation by dose and sex for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible.

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- VIABILITY (OFFSPRING): Describe mean litter size and viability (survival) results from pups during lactation, sex ratio. Also describe anogenital distance results, if measured.
- CLINICAL SIGNS (OFFSPRING): Describe any clinical observations of offspring during lactation.
- BODY WEIGHT (OFFSPRING): Describe offspring body weights and selected mean pup body weight data. Separate data for selected lactation days by generation (F1 and F2).
- SEXUAL MATURATION (OFFSPRING): Describe biologically relevant effects on vaginal opening and preputial separation and other effects on sexual maturation.

- ORGAN WEIGHTS (OFFSPRING): Give absolute and relative organ weight changes as appropriate; relate to any histological findings.
- GROSS PATHOLOGY (OFFSPRING): State treatment-related findings and relate with other findings as appropriate. It is recommended to tabulate treatment-related findings and limit text to integration of findings and highlights.
- HISTOPATHOLOGY (OFFSPRING): State treatment-related findings and relate with other findings as appropriate. It is recommended to tabulate treatment-related findings and limit text to integration of findings and highlights.
- OTHER FINDINGS (OFFSPRING): Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.9.2.1.63. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.9.2.1.64. 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.

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.

7.9.2.1.65. 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.

Tabella E.460. Field Descriptions

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.
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.

7.9.2.1.66. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.9.2.1.67. Conclusions

Enter any conclusions if applicable.

7.9.2.1.68. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.2.1.69. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9.3. [7.8.2] Developmental toxicity / teratogenicity

7.9.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.9.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.9.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.461. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.9.3.1.3. 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.

7.9.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.9.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9.3.1.6. Limit test

Indicate if the experiment was a limit test.

7.9.3.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.462. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.9.3.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.9.3.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.9.3.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.9.3.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.463. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.9.3.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available

- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.9.3.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.9.3.1.14. Species

Select name of species.

7.9.3.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.9.3.1.16. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Housing: describe housing conditions. Indicate whether individual metabolism cages were used.
- 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).

7.9.3.1.17. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.9.3.1.18. Type of inhalation exposure (if applicable)

If route of administration is "inhalation", indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.9.3.1.19. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.9.3.1.20. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.21. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.9.3.1.22. 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.

7.9.3.1.23. Details on mating procedure

Briefly describe the mating procedure.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.24. Duration of treatment / exposure

Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.

7.9.3.1.25. Frequency of treatment

In the case of an inhalation or dermal study include the daily exposure duration, e.g. "4 hours per day". Use of non-standard dosing regime should be justified.

7.9.3.1.26. Duration of test

Indicate the complete duration of the test.

7.9.3.1.27. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.464. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day. You may enter explanatory text.
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Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate, e.g. state whether dosing was based on body weight on the most recent body weight determination or on a specific gestation day.
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7.9.3.1.28. No. of animals per sex per dose

Enter number of females per dose, e.g. "20" or specify according to dose if different numbers were used and explain why.

For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.29. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.9.3.1.30. Further details on study design

Include any further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Use data from range-finding study if available. More comprehensive details may be attached.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.31. Maternal examinations

Indicate if and which examinations were performed in the dams and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.32. Ovaries and uterine content

Indicate if ovaries and uterine contents were examined and the type of examinations.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.33. Fetal examinations

Indicate if and which examinations were performed in the fetuses. Describe in detail, i.e. external, soft tissue and skeletal examinations, including assignment of fetuses and standard/non-standard methodologies used. Indicate how many per litter were used, i.e. all, half, a distinct number, or any other. When tabulating parameters examined, refer to respective table no.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.34. Statistics

List parameters that were analyzed by which test methods. Indicate whether these are appropriate. Differentiate between parametric and non-parametric analysis.

Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.

7.9.3.1.35. Indices

Describe which indices were calculated from cesarean section records of animals in the study. Include formulas or descriptions as provided in the study report.

7.9.3.1.36. Historical control data

Describe whether historical control data were provided to allow comparison with concurrent controls. State source of data and what data were included.

7.9.3.1.37. 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.

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.

7.9.3.1.38. Effect levels

Record effect levels, based on different endpoints and effect types (i.e. maternal toxicity, developmental toxicity). Copy this block of fields as appropriate.

Tabella E.465. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEC or LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEC identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" and specify in the related text field). If the
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	critical effects at a specific dose or concentration level are reported only, select "dose. level:" or "conc. level:" and specify.
Effect type	Select the effect type (e.g. "maternal toxicity") the effect level refers to.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "histopathology: liver enlargement". Select freetext template either for Maternal toxicity or Developmental toxicity. Delete any elements in the predefined freetext that do not apply. This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.

7.9.3.1.39. Maternal toxic effects

Indicate whether any treatment-related maternal effects were observed. In below field "Details on maternal toxic effects", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.3.1.40. Details on maternal toxic effects

Describe the effects if previous field answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Include data on mortality, clinical observations, body weight gain, food consumption, gross pathology, cesarean section observations, other.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.41. Embryotoxic / teratogenic effects

Indicate whether any treatment-related developmental effects were observed. In below field "Details on embryotoxic / teratogenic effects", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.9.3.1.42. Details on embryotoxic / teratogenic effects

Describe the effects if previous field answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Include data on findings from external, visceral and skeletal examinations. Present variations and malformations (or other classifications of anomalies) separately; give the total visceral, skeletal and visceral alterations when applicable.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.43. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.9.3.1.44. 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.

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.

7.9.3.1.45. 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.

Tabella E.466. Field Descriptions

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.
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.

7.9.3.1.46. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.9.3.1.47. Conclusions

Enter any conclusions if applicable.

7.9.3.1.48. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.3.1.49. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9.4. [7.8.3] Toxicity to reproduction: other studies

7.9.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.9.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.9.4.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.467. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate.

	Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.9.4.1.3. 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.

7.9.4.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.9.4.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.9.4.1.6. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.9.4.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.468. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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");
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	<ul style="list-style-type: none"> - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.9.4.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.9.4.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.9.4.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.9.4.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.469. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.9.4.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify

- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.9.4.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.9.4.1.14. Species

Select name of species.

7.9.4.1.15. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.9.4.1.16. Sex

Select as appropriate.

7.9.4.1.17. 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. Consult the programme-specific guidance (e.g. OECD HPVC, 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.
- 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).

7.9.4.1.18. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.9.4.1.19. Type of inhalation exposure (if applicable)

If route of administration is "inhalation", indicate type of inhalation exposure, e.g. "nose only". Any remarks can be entered in the supplementary remarks subfield.

7.9.4.1.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.9.4.1.21. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.4.1.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.9.4.1.23. 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.

7.9.4.1.24. Duration of treatment / exposure

Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.

7.9.4.1.25. 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.

7.9.4.1.26. Duration of test

Indicate the complete duration of the test.

7.9.4.1.27. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.470. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day. You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate, e.g. state whether dosing was based on body weight on the most recent body weight determination or on a specific gestation day.

7.9.4.1.28. No. of animals per sex per dose

Depending on type of study specify either number of dams or number of males and females.

7.9.4.1.29. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.9.4.1.30. Details on study design

Give details on the study design. As an option you may include an excerpt from the study report.

7.9.4.1.31. Statistics

List parameters that were analyzed by which test methods.

7.9.4.1.32. 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.

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.

7.9.4.1.33. Effect levels

Record effect levels, based on different endpoints and/or separated for each generation and/or sex. Copy this block of fields as appropriate.

Tabella E.471. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEL/NOAEC or LOAEL/LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEL identified" or "no NOAEC identified". If a benchmark dose / concentration was calculated, select "BMD" or "BMC" and specify (e.g. "10% response") in the supplementary remarks field. If the critical effects at a specific concentration level are reported only, select "dose level" or "conc. level" and specify in the supplementary remarks field.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Sex	Select from drop-down list.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level.

7.9.4.1.34. Observed effects

Describe any effects observed by dose level.

7.9.4.1.35. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.9.4.1.36. 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.

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.

7.9.4.1.37. 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.

Tabella E.472. Field Descriptions

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.
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.

7.9.4.1.38. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.9.4.1.39. Conclusions

Enter any conclusions if applicable.

7.9.4.1.40. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.9.4.1.41. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10. [7.9] Specific investigations

7.10.1. [7.9.1] Neurotoxicity

7.10.1.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.10.1.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability

score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.10.1.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.10.1.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.10.1.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.10.1.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.10.1.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.10.1.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.473. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.10.1.2.3. 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.

7.10.1.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.10.1.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10.1.2.6. Test type

Select appropriate test type. Note: This field may be redundant with the information given in field "Guideline", but is considered useful for searching reasons.

7.10.1.2.7. Limit test

Indicate if the experiment was a limit test.

7.10.1.2.8. 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. US EPA in addition to OECD guideline).

Tabella E.474. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p>

	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.10.1.2.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.10.1.2.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.10.1.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.10.1.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.475. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.10.1.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.

- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.10.1.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.10.1.2.15. Species

Select name of species. If not available from picklist, select "other" and specify.

7.10.1.2.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.10.1.2.17. Sex

Select as appropriate.

7.10.1.2.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Housing: describe housing conditions. Indicate whether individual metabolism cages were used.
- 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).

7.10.1.2.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.10.1.2.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.10.1.2.21. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.1.2.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.10.1.2.23. 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.

7.10.1.2.24. Details on mating procedure (for developmental toxicity study)

Briefly describe the mating procedure.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.1.2.25. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "28 days" or "18 months".

7.10.1.2.26. 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.

7.10.1.2.27. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.476. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. "0, 112, 220, 523 mg/kg bw/day (m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.10.1.2.28. No. of animals per sex per dose

Enter value or specify according to dose if different number of animals per dose or test, e.g. "10 in each dose group of FOB".

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").

For a developmental neurotoxicity study it should be noted: The method of animal assignment should have minimized potential problems related to litter effects, i.e., by using one pup/sex/litter (or one measure/litter, e.g., mean body weight for each litter).

When allocating animals to FOB and motor activity testing, the same individual animals should have been evaluated at all scheduled time points.

For the selection of animals and testing paradigms for cognitive (learning and memory) assessment, it is important to ensure that tasks were selected and/or animals allocated so that comparable assessments of learning were made at both times, i.e., shortly after PND 21 and around PND 60. Indicate whether the same or different animals were used for assessments at the weanling and adult ages. In general, the use of separate animals at the two time points is

preferred, because for many tasks, initial learning (PND 21) may confound later (PND 60) assessment of learning. If the same animals were used at both times, different tasks would likely have been necessary. The selection of the test for assessing learning should have been adequately justified regardless of whether the same or a different task was used.

7.10.1.2.29. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.10.1.2.30. Further 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

For a developmental neurotoxicity study it should be noted: Dose selection rationale should be discussed, including information from the prenatal developmental or two-generation reproduction studies, if applicable. Any pilot study data (including biomarker data, such as cholinesterase activity) or pharmacokinetic data (e.g., milk or blood levels of test substance, or data that established time of peak effect) should be described in detail. If these data were submitted in a separate study report, the methods and results (including detailed tables of analytical results) should be presented in a separate record (include a reference in field "Cross-reference to same study" or "Cross-reference to other study" as applicable); alternatively, they could be appended to this record.

7.10.1.2.31. Observations and clinical 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. When tabulating parameters examined, refer to respective table no.

If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.1.2.32. Specific biochemical examinations

If specific biochemical determinations were made, provide details on the sampling, the tissues tested (e.g. plasma, whole blood, RBCs, brain (whole brain or regions)) and methodology. When tabulating parameters examined, refer to respective table no.

Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.1.2.33. Neurobehavioural examinations performed and frequency

Provide details on the neurobehavioural examinations performed and frequency. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

7.10.1.2.34. Sacrifice and (histo)pathology

Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined.

Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

Specific guidance for acute or subchronic neurotoxicity:

Indicate when and how were animals sacrificed, how many were perfused, what parameters were measured (e.g. brain weight, length and width), what were the procedures for perfusion, what tissues were evaluated, what type of staining was used, how were sections prepared (thickness, embedding media, number of sections). How many animals from each sex and treatment group were evaluated?

Specific guidance for developmental neurotoxicity studies: see freetext template.

Tables are optional, particularly for postmortem examinations of the offspring and the specific morphometric measures taken.

7.10.1.2.35. Litter observations

For developmental neurotoxicity studies, indicate the relevant developmental landmarks and details on postweaning and litter observations. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study

summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Specific guidance on DEVELOPMENTAL LANDMARKS: If other developmental landmarks than those specified in the guideline are included in the study report, a detailed description of any developmental landmarks evaluated is MANDATORY, e.g., eye opening, pinna unfolding, incisor eruption, etc.

7.10.1.2.36. Pharmacokinetic data

For developmental neurotoxicity studies, provide pharmacokinetic data. If applicable] Measures of [list parameters examined, e.g., test substance and metabolites in milk or in maternal, fetal, or pup blood] were determined in [Provide study identification, source of the animals (e.g., were they part of a range-finding or companion study?). Describe how many animals of each age group at each time point, how often, at what age for offspring. Indicate specifics of sample collection and processing; describe analytical methods used.

7.10.1.2.37. Other examinations

Describe any other examinations.

7.10.1.2.38. Positive control

Briefly describe the positive control data cited, and its acceptability for use with the current study.

For positive control data to be acceptable, it must demonstrate the sensitivity of the test method to detect changes in the measured parameters. These data do not have to be from studies using prenatal exposures. However, the laboratory must demonstrate competence in evaluation of effects in neonatal animals perinatally exposed to chemicals and establish test norms for the appropriate age group. For observational measures, the data should demonstrate the ability to detect major neurotoxic endpoints, including limb weakness, paralysis, tremor, and autonomic signs; motor activity positive control data should demonstrate the ability to detect both increases and decreases in motor activity; pathology positive control data should demonstrate the ability to detect central and peripheral nervous system pathology (separate groups may be used to demonstrate each type of pathology, for example, acrylamide for peripheral nervous system pathology and trimethyl tin for central nervous system pathology).

The methods should be completely described, and must be the same as those used in the study being evaluated (for example, the same equipment should be used, motor activity sessions should be of the same duration, the observation arena should be the same, the same sections should be evaluated for neuropathology, using the same types of stains, etc.), and preferably the same personnel should have conducted the testing. The data presentation should be complete enough to evaluate the sensitivity of the method, including individual data and measures of variability. Statistical evaluations used to demonstrate sensitivity should also be the same as those used in the study being evaluated. The number of animals per test group should not be greater than that used in the study under evaluation. Positive control data should also demonstrate inter-observer reliability for the FOB (i.e., the same results should be seen regardless of who is doing the observations). The positive control data should have been collected within a reasonable time frame before the current study, e.g., the last few years. New data should also be collected when observational personnel or other critical laboratory elements change.

7.10.1.2.39. 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.

7.10.1.2.40. 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.

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.

7.10.1.2.41. Effect levels

Record effect levels, based on different endpoints and/or separated for each generation (if applicable) and/or sex. Copy this block of fields as appropriate.

Tabella E.477. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEC or LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEC identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" 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.
Generation (if applicable)	For developmental neurotoxicity study, select the generation (i.e. "maternal" or "offspring"). If not applicable, leave this subfield empty.
Sex	Select from drop-down list.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level. If necessary, give further details. Delete any elements in the predefined freetext that do not apply.

	This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.
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7.10.1.2.42. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.43. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.44. Food consumption and compound intake (if feeding study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.45. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.46. Water consumption and compound intake (if drinking water study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.10.1.2.47. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.48. Biochemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.49. Neurobehavioural results

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.50. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.51. Neuropathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.52. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.

- WATER CONSUMPTION AND COMPOUND INTAKE (if drinking water study): Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

- BIOCHEMISTRY: Provide separate tables for blood and brain cholinesterase activity and, if determined, for other enzyme activities (i.e. NTE for delayed neurotoxicity of organophosphorus substances). Include all data for whole brain (if brain regions were evaluated, also include all data from cortex and hippocampus; for other regions include data from all time points if statistically significant changes were found for a particular region or if changes from baseline of 20% or greater were seen).

- NEUROBEHAVIOUR: Provide separate tables for functional observation battery results, motor activity, auditory startle field and learning and memory testing results as appropriate. Data should be included for all statistically significant findings, and for any findings that could be toxicologically relevant (even if not statistically significant). If significant effects are found, data from all groups, time points, and both sexes should be included for that parameter. Include severity information if there are changes in severity. Duplicate the tables as necessary to include different types of findings (e.g. activity levels, landing foot splay, etc.).

- GROSS PATHOLOGY: Give absolute AND relative brain weights as appropriate.

- NEUROPATHOLOGY: Describe what types of lesions were found. If neuropathological alterations were observed in the high dose group, were lower dose groups sequentially examined? If evidence of neuropathological alterations was seen, was a subjective diagnosis (dose-blind coded re-reading) conducted? If treatment-related lesions were found, include information in a table, including information regarding lesion severity; if no treatment-related lesions were found, include some information in text regarding reported incidence of lesions unrelated to treatment and in control groups.

- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.10.1.2.53. Reproductive performance (parental animals)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.54. Viability (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.55. Sexual maturation (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.56. Developmental landmarks (offspring)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.1.2.57. Details on results (for developmental neurotoxicity)

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible.

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- REPRODUCTIVE PERFORMANCE (PARENTAL ANIMALS): Describe the effects by dose level as stated above. Summarise any biologically relevant effects on reproductive performance. Any table included should be based on report content and include any calculated reproductive indices.
- VIABILITY (OFFSPRING): Describe, for each generation and sex, the effects at the different doses, i.e. mean litter size and viability (survival) results from pups during lactation. Also describe anogenital distance results, if measured.

- SEXUAL MATURATION (OFFSPRING): Describe the effects by dose level as stated above. Summarize any biologically relevant effects on vaginal opening and balanopreputial separation. Describe findings on sexual maturation.
- DEVELOPMENTAL LANDMARKS (OFFSPRING): For developmental neurotoxicity studies, describe the effects at the different doses in the supplementary remarks field.
- OTHER FINDINGS: Describe the results of any other examinations.

7.10.1.2.58. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.10.1.2.59. 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.

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.

7.10.1.2.60. 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.

Tabella E.478. Field Descriptions

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.
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.

7.10.1.2.61. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.10.1.2.62. Conclusions

Enter any conclusions if applicable.

7.10.1.2.63. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.1.2.64. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10.2. [7.9.2] Immunotoxicity

7.10.2.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.10.2.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.10.2.1.2. Key parameter (optional)

The field(s) under this heading (if provided) can be optionally completed in order to specify the key parameter(s) that may subsequently be used in the chemical safety assessment, classification and labelling or other. In order to enable the use of any specific software, only a minimum number of structured and hence, searchable fields are provided, in many cases only one.

Key parameters are intended to condense the data summarised in field "Full short description of relevant endpoint data" to one single numeric value or concluding remark (e.g. negative / positive) chosen from a drop-down list. Where a numeric field is provided, only a clear value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit as indicated in the field label (e.g. mg/L) may be required.

If the key value is no clear number, but a range or preceded by <, <=, >, or >=, you may either leave this field empty or make up a value you consider most appropriate for the intended subsequent purpose. The rationale for any user-derived values should be described in field "Discussion" for the sake of transparency. Some non-exhaustive examples of user-derived parameters are as follows:

- Aquatic short-term L(E)C50 >100 mg/L (e.g. because only tested up to water solubility of the substance): it may be appropriate to assume 100 mg/L as worst case value.
- Aquatic long-term LOEC 1 mg/L (>10 and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC.
- Acute oral LD50 >2000 mg/kg b.w. (because no LD50 was achieved in a limit test): enter 2000 mg/kg b.w.

7.10.2.1.3. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.10.2.1.4. Justification for classification or non-classification

Provide an appropriate justification for the classification proposed or, when relevant, for the non-classification of the substance.

7.10.2.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.10.2.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.10.2.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.479. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.10.2.2.3. 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.

7.10.2.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.10.2.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10.2.2.6. Test type

Select appropriate test type.

7.10.2.2.7. Limit test

Indicate if the experiment was a limit test.

7.10.2.2.8. 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. US EPA in addition to OECD guideline).

Tabella E.480. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.10.2.2.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.10.2.2.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.10.2.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.10.2.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.481. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.10.2.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.10.2.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.10.2.2.15. Species

Select name of species. If not available from picklist, select "other" and specify.

7.10.2.2.16. Strain

Select strain as appropriate. If not available from picklist, select "other" and specify.

7.10.2.2.17. Sex

Select as appropriate.

7.10.2.2.18. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Housing: describe housing conditions. Indicate whether individual metabolism cages were used.
- 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).

7.10.2.2.19. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.10.2.2.20. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.10.2.2.21. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.22. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.10.2.2.23. 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.

7.10.2.2.24. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "28 days" or "18 months".

7.10.2.2.25. 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.

7.10.2.2.26. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.482. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. "0, 112, 220, 523 mg/kg bw/day (m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.10.2.2.27. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.28. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.10.2.2.29. Further 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.30. Observations and clinical examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in field "Cross-reference to same study" 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.31. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.32. Cell viabilities

Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.33. Humoral immunity examinations

Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Example of brief description of protocol: "Spleen IgM antibody response to a T-dependent antigen, sheep erythrocytes (sRBC) - Day 4 response: Animals were exposed to the test substance or positive control for 28 days, then injected intravenously to sheep erythrocytes on day 25. On day 29 (peak day of IgM response), the animals were sacrificed, spleens were removed and weighed, then spleen cells were prepared on day 30. The primary response to sheep erythrocytes was measured using a modified hemolytic plaque assay (Jerne, N.K., et al., Plaque forming cells: Methodology and Theory. Transpl. Rev. 18:130-191, 1974). Cell counts were performed and the number of cells/spleen, AFC/spleen and AFC/106 spleen cells were determined."

Example of brief description of protocol for Enzyme-Linked Immunosorbent Assay (ELISA): "The effects of test substance on antibody response to antigen were determined by an ELISA using methods described by Temple et al. (1995). Test animals were dosed with test material for ... days. Animals were exposed to sheep erythrocytes on day...IgM titers in serum were determined ... days after immunization. "

7.10.2.2.34. Specific cell-mediated immunity

Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Describe cell harvest and culture and proliferation measurement ((³H) thymidine) incorporation, etc.

7.10.2.2.35. Non-specific cell-mediated immunity

Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Example of brief description of protocol: "Following ... days of exposure to test material or positive control, the effects of test substance on spontaneous cytotoxic activity were determined by incubating splenocytes from treated and control animals with ⁵¹Cr-labeled YAC-1 lymphoma cells (target cell). Following a 4-hour incubation period, the amount of radiolabel released from target cells was determined (measure of NK cytotoxicity)."

7.10.2.2.36. Other functional activity assays

Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined.

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Example of brief description of protocol: "On day 30, a single cell suspension was prepared from each spleen and incubated in flat bottom microtiter plates (RPMI media supplemented with 10% fetal bovine serum and 5x10⁻⁵ 2-mercaptoethanol). The spleen cells were cultured in either non-treated or anti-CD3-treated wells (100 µL of 1 µg/mL anti-CD3) and incubated at 4°C overnight. Prior to harvest on day 3, the cells were pulsed with 3H-thymidine for 18-24 hours."

Example of brief description of protocol for enumeration total B cells, total T cells and T cell subpopulations: "Following ... days of dosing, single cell preparations from each spleen were seeded at 1x10⁶ cells/well into a 96-well microtiter plate. Phenotypic analysis of total B cell, T cell, and T cell subpopulations were conducted using monoclonal antibody conjugates to fluorescein isothiocyanate (FITC) or phycoerythrin (PE). The specific monoclonal antibodies used were: OX19 conjugated to PE to enumerate total T-cells (CD5+), OX38 conjugated to FITC to enumerate CD4+ cells (T helper cells) and OX8 conjugated to FITC to enumerate CD8+ cells (T suppressor/cytotoxic cells). For both the CD4+ and CD8+ cells, a double label with OX19 was used. OX33 conjugated to FITC was used to enumerate CD45+ (B lymphocytes). Following the initial staining with antibody and washing with staining buffer, the DNA specific fluorescent stain propidium iodide (PI) was added to each well as a viability stain. Following a 5 minute incubation with PI, the cells were washed once with staining buffer and then enumerated on a Coulter Epics XL-MCL Flow Cytometer. At least 5,000 cells were counted for each sample."

7.10.2.2.37. Other examinations

Describe any other examinations.

7.10.2.2.38. 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.

7.10.2.2.39. 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.

7.10.2.2.40. 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.

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.

7.10.2.2.41. Effect levels

Record effect levels, based on different endpoints and/or separated for for males and females. Copy this block of fields as appropriate.

Tabella E.483. Field Descriptions

Endpoint	Select type of endpoint, normally NOAEC or LOAEC. If adverse effects were observed at the highest dose tested, select "no NOAEC identified". If a benchmark dose / concentration was calculated, select appropriate BMC indicator (e.g. "BMC05" or "BMC:" 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.
Sex	Select from drop-down list.
Effect level	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Unit of dose (no label)	Select unit of dose or concentration as appropriate.
Basis for effect level / Remarks	Indicate the parameter(s) used to establish the given effect level. If necessary, give further details, e.g. "cell viability (spleen); humoral immunity (ELISA)". Delete any elements in the predefined freetext that do not apply. This subfield can also be used to enter any other explanations, e.g. for indicating that the effect level provided was derived by the notifier or for indicating "NOAEL = highest dose tested" if applicable.

7.10.2.2.42. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.43. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.44. Food consumption and compound intake (if feeding study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.45. Food efficiency

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.46. Water consumption and compound intake (if drinking water study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.10.2.2.47. Ophthalmoscopic examination

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.48. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.49. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.50. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.51. Gross pathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.52. Cell viabilities

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.53. Humoral immunity examinations

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.54. Specific cell-mediated immunity

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.55. Non-specific cell-mediated immunity

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.56. Other functional activity assays

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.57. Other findings

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.10.2.2.58. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Relate treatment-related findings to any histological findings where appropriate.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

Explanations:

- CLINICAL SIGNS AND MORTALITY: Describe the effects by dose level as stated above. Clinical signs include gross observations for behaviour and appearance ("cage-side observations"). Note when signs were first observed and if they were reversible. For mortalities the cause of death should be indicated.
- BODY WEIGHT AND WEIGHT GAIN: Describe the effects by dose level as stated above.
- FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study): Describe the effects by dose level as stated above.
- FOOD EFFICIENCY: Describe the effects by dose level as stated above.
- WATER CONSUMPTION AND COMPOUND INTAKE (if drinking water study): Describe the effects by dose level as stated above. Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.
- OPHTHALMOSCOPIC EXAMINATION: Describe the effects by dose level as stated above.
- HAEMATOLOGY: Describe the effects by dose level as stated above.
- CLINICAL CHEMISTRY: Describe the effects by dose level as stated above.
- URINALYSIS: Describe the effects by dose level as stated above.
- GROSS PATHOLOGY: Describe the effects by dose level as stated above. Give absolute and relative organ weights as appropriate and relate to any histological changes. Limit text to integration of findings and highlights and refer to respective table no. (use predefined table if any).
- CELL VIABILITIES: Describe the effects by dose level as stated above. Specify organ (spleen, thymus, bone marrow) and describe the effects at the different doses.
- HUMORAL IMMUNITY EXAMINATIONS: Describe the effects by dose level as stated above.
- SPECIFIC CELL-MEDIATED IMMUNITY: Describe the effects by dose level as stated above.
- NON-SPECIFIC CELL-MEDIATED IMMUNITY: Describe the effects by dose level as stated above.
- OTHER FUNCTIONAL ACTIVITY ASSAYS: Describe the effects by dose level as stated above.
- OTHER FINDINGS: Describe the results of any other examinations or include a cross-reference in field "Cross-reference to same study" to indicate that specific results of the same study are described in another chapter.

7.10.2.2.59. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.10.2.2.60. 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.

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.

7.10.2.2.61. 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.

Tabella E.484. Field Descriptions

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.
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.

7.10.2.2.62. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.10.2.2.63. Conclusions

Enter any conclusions if applicable.

7.10.2.2.64. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.2.2.65. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10.3. [7.9.3] Specific investigations: other studies

7.10.3.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.10.3.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)

- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)

- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.10.3.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.10.3.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.10.3.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.10.3.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.485. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.10.3.2.3. 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.

7.10.3.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.10.3.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.10.3.2.6. Type of effects studied

Indicate the type of effects studied. As appropriate, include further specification in the supplementary remarks field.

In the supplementary remarks field, include any relevant remarks, e.g. indicate which data point or findings the special study was intended to address if applicable. If the results recorded are part of a study recorded in another record/section (e.g. Repeated dose toxicity), include a note in field "Cross-reference to same study" and refer to that summary.

7.10.3.2.7. Type of method

Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field "Any other information on materials and methods incl. tables". If a specific template for in vitro assays is provided include the data in that template instead.

7.10.3.2.8. 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. Copy this field as appropriate.

7.10.3.2.9. 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. US EPA in addition to OECD guideline).

Tabella E.486. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.10.3.2.10. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.10.3.2.11. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.10.3.2.12. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.10.3.2.13. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.487. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.10.3.2.14. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.10.3.2.15. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.10.3.2.16. 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 "Exposure related observations".

7.10.3.2.17. Strain

Select as appropriate. If not available from picklist, select "other" and specify.

7.10.3.2.18. Sex

Select as appropriate.

7.10.3.2.19. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Housing: describe housing conditions. Indicate whether individual metabolism cages were used.

- 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).

7.10.3.2.20. Route of administration

Select as appropriate. If not available from picklist, select "other" and specify.

7.10.3.2.21. Vehicle

Select "unchanged (no vehicle)" if none was used or select vehicle used if any. If not available from picklist, select "other" and specify.

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.10.3.2.22. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.3.2.23. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.10.3.2.24. 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.

7.10.3.2.25. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "28 days" or "18 months".

7.10.3.2.26. 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.

7.10.3.2.27. Post exposure period

Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.

7.10.3.2.28. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.488. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. "0, 112, 220, 523 mg/kg bw/day (m/f)" or "0, 112, 220, 523 mg/kg bw/day (m); 0, 87, 198, 477 mg/kg bw/day (f)". You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.10.3.2.29. 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 provide a detailed table on the animal assignment and refer to respective table no. (use predefined table if any).

7.10.3.2.30. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.10.3.2.31. Further details on study design

Include details on the study design as appropriate.

7.10.3.2.32. Examinations

Include details on the examinations performed.

7.10.3.2.33. 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.

7.10.3.2.34. 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.

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.

7.10.3.2.35. Details on results

Describe the results.

If the results recorded are part of a study recorded in another record/section (e.g. Repeated dose toxicity), include a note in field "Cross-reference to same study" and refer to that summary.

7.10.3.2.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.10.3.2.37. 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.

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.

7.10.3.2.38. 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.

Tabella E.489. Field Descriptions

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.
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.

7.10.3.2.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.10.3.2.40. Conclusions

Enter any conclusions if applicable.

7.10.3.2.41. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.10.3.2.42. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11. [7.10] Exposure related observations in humans

7.11.1. [7.10.1] Health surveillance data

7.11.1.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.11.1.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.11.1.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.490. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.

Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.
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7.11.1.1.3. 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.

7.11.1.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.11.1.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.1.1.6. Study type

Indicate 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.
- Other: any other type of study or information, e.g. self-reported symptoms.

7.11.1.1.7. 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. Copy this field as appropriate.

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.

7.11.1.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.491. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.11.1.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.11.1.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.11.1.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.11.1.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.492. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.11.1.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.11.1.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.11.1.1.15. Type of population

Indicate whether subjects of the general population or from an occupational environment were investigated. If both were included in the same study, duplicate this field and indicate both types. If two independent studies are reported by the same report, use two separate records.

7.11.1.1.16. 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.

7.11.1.1.17. 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.

7.11.1.1.18. 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.

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.

7.11.1.1.19. Results

Describe the results of the health surveillance study. In addition, include or attach tables and/or an excerpt from the study report.

7.11.1.1.20. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.11.1.1.21. 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.

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.

7.11.1.1.22. 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.

Tabella E.493. Field Descriptions

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.
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.

7.11.1.1.23. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.11.1.1.24. Conclusions

Enter any conclusions if applicable.

7.11.1.1.25. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.11.1.1.26. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.2. [7.10.2] Epidemiological data

7.11.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.11.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.11.2.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.494. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.11.2.1.3. 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.

7.11.2.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.11.2.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.2.1.6. Study type

Select appropriate study type.

7.11.2.1.7. 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. Copy this field as appropriate.

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.

7.11.2.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.495. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<p>- To indicate if a the study was performed prior to the adoption of the test guideline specified;</p> <p>- To indicate if the methodology used was based on an extension of the test guideline specified.</p>
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.11.2.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.11.2.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.11.2.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.11.2.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.496. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.11.2.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %

- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.11.2.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.11.2.1.15. Type of population

Indicate whether subjects of the general population or from an occupational environment were investigated. If both were included in the same study, duplicate this field and indicate both types. If two independent studies are reported by the same report, use two separate records.

7.11.2.1.16. Ethical approval

For ethical reasons 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.

7.11.2.1.17. Details on study design

Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

Explanations:

- HYPOTHESIS TESTED: If study type is cohort or case control study, state the hypothesis(es) tested in this study.

- STUDY PERIOD: Give dates during which the data were collected (from ... to ...)

- SETTING: Indicate the setting where this study took place, e.g., occupational, residential, hospital-based, clinical practice, environmental (e.g., fence line of waste sites, air monitoring); its geographic location(s); and any other pertinent information.

- STUDY POPULATION: Include details on the study population using the predefined items and inserting additional ones if required. Alternatively include or attach a table and refer to respective Table no.

- COMPARISON POPULATION: Indicate one of the predefined types; delete those being not applicable. Provide details, e.g., note the parameters that were "matched" (i.e., smoking, age, sex, etc.).

- HEALTH EFFECTS STUDIED: Describe as appropriate. Note whether the diagnosis of the effects was made blind to exposure status. Alternatively include or attach a table and refer to respective Table no.

7.11.2.1.18. Exposure assessment

Indicate whether the exposure was measured or estimated.

For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.

7.11.2.1.19. Details on exposure

Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

Explanations:

- TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces.
- TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable.
- EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels.
- EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other.
- POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted.
- DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.

7.11.2.1.20. Statistical methods

Describe all statistical methods used and the data to which they were applied (include sample size and power calculations, if available).

7.11.2.1.21. 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.

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.

7.11.2.1.22. Results

Provide exposure data as available. Give numbers of cases for each effect/disease/parameter under consideration, include measures of disease frequency (SMRs, ORs, PMRs, RR, prevalence, incidence, adjusted and/or crude rates), correlations, distributions etc., statistical data (significance, confidence intervals).

If appropriate present the data in tabular form. Upload predefined table in the rich text field "Any other information on results incl. tables" or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

7.11.2.1.23. Confounding factors

Indicate any (possible) confounding factor(s), e.g. multi chemical exposure or smoking, and discuss their influence on the observed causal association.

7.11.2.1.24. Strengths and weaknesses

Explain findings and discuss any other factors, i.e. bias, validity issues, reliability issues (including the adequacy of the exposure estimation or measurements), representativeness concerns, unique nature of study, influence of past exposures, latency, turnover rates in occupation studies.

7.11.2.1.25. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.11.2.1.26. 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.

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.

7.11.2.1.27. 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.

Tabella E.497. Field Descriptions

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.
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.
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7.11.2.1.28. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.11.2.1.29. Conclusions

Enter any conclusions if applicable.

7.11.2.1.30. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.11.2.1.31. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.3. [7.10.3] Direct observations: clinical cases, poisoning incidents and other

7.11.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.11.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.11.3.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.498. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.11.3.1.3. 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.

7.11.3.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.11.3.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.3.1.6. Study type

Select type of medical data.

7.11.3.1.7. 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. Copy this field as appropriate.

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.

7.11.3.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.499. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.11.3.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.11.3.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.11.3.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.11.3.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.500. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.11.3.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.11.3.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.11.3.1.15. Type of population

Indicate whether subjects of the general population or from an occupational environment were investigated. If both were included in the same study, duplicate this field and indicate both types. If two independent studies are reported by the same report, use two separate records.

7.11.3.1.16. 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.

7.11.3.1.17. Ethical approval

In the case of a study with volunteers 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.

7.11.3.1.18. Route of exposure

Indicate the route of exposure. If more than one, copy this field.

7.11.3.1.19. Reason of exposure

Indicate the reason of exposure.

7.11.3.1.20. Exposure assessment

Indicate whether the exposure was measured or estimated.

For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.

7.11.3.1.21. 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 substance ingested, dermal contact etc. Include methods of analysis if data available.

If exposure was estimated, describe how this was done, if available.

7.11.3.1.22. 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.

7.11.3.1.23. Medical treatment

Indicate if and what medical treatment exposed / intoxicated persons received.

7.11.3.1.24. 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.

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.

7.11.3.1.25. Clinical signs

Describe any relevant signs and symptoms observed.

7.11.3.1.26. 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.

7.11.3.1.27. Effectivity of medical treatment

Indicate whether and during what time intoxicated persons responded to medical treatment.

7.11.3.1.28. 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.

7.11.3.1.29. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.11.3.1.30. 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.

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.

7.11.3.1.31. 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.

Tabella E.501. Field Descriptions

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.
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.

7.11.3.1.32. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.11.3.1.33. Conclusions

Enter any conclusions if applicable.

7.11.3.1.34. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.11.3.1.35. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.4. [7.10.4] Sensitisation data (humans)

7.11.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.11.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data

characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.11.4.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.502. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.

Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.11.4.1.3. 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.

7.11.4.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.11.4.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.4.1.6. Type of sensitisation studied

Indicate whether respiratory or skin sensitisation was studied. If both, duplicate this field.

7.11.4.1.7. Study type

Select type of study.

7.11.4.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.503. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.11.4.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.11.4.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.11.4.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.11.4.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.504. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.11.4.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable

- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.11.4.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.11.4.1.15. Type of population

Indicate whether subjects of the general population or from an occupational environment were investigated. If both were included in the same study, duplicate this field and indicate both types. If two independent studies are reported by the same report, use two separate records.

7.11.4.1.16. Ethical approval

In the case of a study with volunteers 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.

7.11.4.1.17. 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.

7.11.4.1.18. 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.

7.11.4.1.19. Controls

Indicate control or reference group or other comparison group and application of control/reference substances.

7.11.4.1.20. Route of administration

Indicate the route of administration.

7.11.4.1.21. 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.

7.11.4.1.22. 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.

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.

7.11.4.1.23. 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.

Give number of persons with positive / negative / equivocal reactions vs. number of study population or volunteers. 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.

7.11.4.1.24. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.11.4.1.25. 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.

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.

7.11.4.1.26. 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.

Tabella E.505. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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7.11.4.1.27. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.11.4.1.28. Conclusions

Enter any conclusions if applicable.

7.11.4.1.29. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.11.4.1.30. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.5. [7.10.5] Exposure related observations in humans: other data

7.11.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.11.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.11.5.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.506. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific

	<p>journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.11.5.1.3. 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.

7.11.5.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.11.5.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.11.5.1.6. Type of information

Briefly indicate the type of information (which does not fit into any of the specific chapter.)

7.11.5.1.7. 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. Copy this field as appropriate.

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.

7.11.5.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.507. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

7.11.5.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.11.5.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.11.5.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.11.5.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.508. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.11.5.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available

- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.11.5.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.11.5.1.15. 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.

7.11.5.1.16. Details on study design

Describe the study design including any relevant information from a study report, publication or other source. Include or attach tables or excerpts from study report as appropriate.

7.11.5.1.17. Exposure assessment

Indicate whether the exposure was measured or estimated.

For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.

7.11.5.1.18. Details on exposure

Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

Explanations:

- TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces.

- TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable.
- EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels.
- EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other.
- POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted.
- DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.

7.11.5.1.19. 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.

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.

7.11.5.1.20. Results

Provide exposure data as available and describe any relevant outcome of the study. If appropriate present the data in tabular form and/or attach excerpt(s) from the study report.

7.11.5.1.21. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.11.5.1.22. 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.

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.

7.11.5.1.23. 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.

Tabella E.509. Field Descriptions

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.
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.

7.11.5.1.24. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.11.5.1.25. Conclusions

Enter any conclusions if applicable.

7.11.5.1.26. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.11.5.1.27. Cross-reference to other study

A Cross-reference to other study or other studys can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studys is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.12. [7.11] Toxic effects on livestock and pets

7.12.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

7.12.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

7.12.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

7.12.2. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.12.2.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.12.2.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.510. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.12.2.3. 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.

7.12.2.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.12.2.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.12.2.6. Limit test

Indicate if the experiment was a limit test.

7.12.2.7. 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. US EPA in addition to OECD guideline).

Tabella E.511. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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7.12.2.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.12.2.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.12.2.10. Reason/justification of study

Briefly describe the reason and justification why toxicity testing with livestock or pets was done. For example, state that the test was required because the substance in question is used in spaces in which animals are housed, kept or transported or exposure is possible via drinking water or feedingstuffs. It should also be stated whether the purpose of the test was to establish an adequate margin of safety (rather than a NOEL of toxicity) and that non-lethal doses were selected (if so).

If the information presented is an estimation of toxic effects based on other available data (as should be indicated in field "Test result type", use either any of the specific fields (as far as possible) or include the information in fields "Remarks: method and test conditions", "Remarks: results" and/or "Remarks: any other information" as appropriate. This information may include data on adverse incidents in farm animals and pets.

7.12.2.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.12.2.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.512. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.12.2.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.12.2.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

7.12.2.15. Species

Select name of species. If not available from picklist, select "other" and specify.

7.12.2.16. Sex

Select as appropriate.

7.12.2.17. Details on test animals and environmental conditions

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.

7.12.2.18. Route of exposure

Indicate to which route of exposure the information or description of experimental study refers to.

7.12.2.19. Vehicle

Select the vehicle used. If not available from picklist, select "other" and specify. If no vehicle was used, select "unchanged (no vehicle)".

Note that some of the vehicles provided in this list are used for specific routes of administration only.

7.12.2.20. Details on exposure

Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.12.2.21. Analytical verification of doses or concentrations

Indicate whether the doses or concentrations were analytically verified.

7.12.2.22. 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.

7.12.2.23. Duration of treatment / exposure

Indicate duration in days, weeks or months, e.g. "5 days" or "10 weeks".

7.12.2.24. 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"). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.

7.12.2.25. Post exposure period

Indicate observation period (in days, weeks, months) after last exposure to the test material.

7.12.2.26. Doses / concentrations

Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields if the dose/concentration levels were determined on more than one basis of quantity as appropriate.

Tabella E.513. Field Descriptions

Doses / concentrations (no label)	Indicate the doses or concentrations including unit applied to the test animals, e.g. 0, 112, 220, 523 mg/kg bw/day. You may enter explanatory text.
Basis	Indicate whether doses/concentrations are based on nominal or actually ingested or analytically measured values. In the supplementary remarks field provide further details as appropriate.

7.12.2.27. No. of animals per sex per dose

Enter value or specify if different number of animals were used per sex and/or dose level.

7.12.2.28. Control animals

Indicate whether and what type of concurrent control groups were used. If not available from picklist, select "other" and specify. Copy field if more than one type of control was used.

7.12.2.29. Further 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.12.2.30. Observations and examinations performed and frequency

Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. "... see Table 1").

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

7.12.2.31. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.12.2.32. Other examinations

Describe any other examinations.

7.12.2.33. 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.

7.12.2.34. 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.

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.

7.12.2.35. Clinical signs and mortality

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.36. Body weight and weight gain

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.37. Food consumption and compound intake (if feeding study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.38. Water consumption and compound intake (if drinking water study)

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.

7.12.2.39. Haematology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.40. Clinical chemistry

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.41. Urinalysis

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.42. Gross pathology and organ weights

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.43. Histopathology

Indicate whether any treatment-related effects were observed. In below field "Details on results", describe the effects by dose (if "yes") or provide any further explanation (if "no effects"), e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

7.12.2.44. Details on results

Describe the effects by dose level for each of the previous fields answered "yes". If answered "no effects", you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why).

Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

Particularly with comprehensive data, include a table in the rich text field "Any other information on results incl. tables" and refer to respective table no., e.g. "see Table 1" (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).

NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.

7.12.2.45. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.12.2.46. 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.

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.

7.12.2.47. 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.

Tabella E.514. Field Descriptions

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.
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.

7.12.2.48. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.12.2.49. Conclusions

Enter any conclusions if applicable.

7.12.2.50. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.12.2.51. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.13. [7.12] Additional toxicological information

7.13.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

7.13.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

7.13.1.2. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.515. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

7.13.1.3. 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.

7.13.1.4. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

7.13.1.5. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

7.13.1.6. Type of 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, hematotoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.

7.13.1.7. 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. US EPA in addition to OECD guideline).

Tabella E.516. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

7.13.1.8. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

7.13.1.9. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

7.13.1.10. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

7.13.1.11. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.517. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

7.13.1.12. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

7.13.1.13. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

7.13.1.14. 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.

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.

7.13.1.15. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

7.13.1.16. 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.

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.

7.13.1.17. 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.

Tabella E.518. Field Descriptions

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.
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.

7.13.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

7.13.1.19. Conclusions

Enter any conclusions if applicable.

7.13.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

7.13.1.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

8. [8] Analytical methods

8.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

8.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.1 Administrative data.

8.1.2. Additional information

Please note: 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.

In other than residue analyses, the method and results should be described in the fields for Data collection method. Fields being not applicable can be ignored.

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 and other relevant details.

8.1.3. 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.

8.1.4. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.519. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M &

	<p>Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate.</p> <p>Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.</p>
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	<p>Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination.</p> <p>Example 1 (journal): J. Agric. Food Chem. 38: 215-227</p> <p>Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.</p>
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

8.1.5. 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.

8.1.6. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

8.1.7. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

8.1.8. 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. Consult with the programme-specific guidance (e.g. EU BPD, OECD HPVC, Pesticides NAFTA or EU REACH) as to what matrices need to be addressed. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices.

8.1.9. 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. US EPA in addition to OECD guideline).

Tabella E.520. Field Descriptions

Qualifier	Select appropriate qualifier, i.e. - "according to" (if a given test guideline was followed);
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	<ul style="list-style-type: none"> - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

8.1.10. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

8.1.11. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

8.1.12. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

8.1.13. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.521. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

8.1.14. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable

- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

8.1.15. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

8.1.16. Details on properties of test surrogate or analogue material

ONLY if the study summary is a read-across to another substance, i.e. analogue or surrogate (e.g. degradation / transformation product), enter any relevant details on the physico-chemical or other relevant properties. Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding chapters (templates) and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

8.1.17. Instrument / detector for data collection

Indicate the instrument / detector used for the quantitative analysis of the parent compound / transformation products including the type of detector, e.g. "HPLC-UV". Copy this field if more than one method needs to be specified.

Give any further details in field "Details on data collection method".

8.1.18. Details on data collection 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. As an option you may include an excerpt from the study report.

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 HPVC, Pesticides NAFTA or EU REACH) thereof. If further details are required, insert (sub)headings as appropriate, e.g.:

INSTRUMENTATION

- Make(s)/model(s) of instrumentation used:
- Specificity of detector(s):
- Columns (packing material, size):
- Carrier gases: for GC:
- Operating procedures:
- Mobile phase for HPLC:
- Retention times for substance and standards:

CHROMATOGRAMS: see Fig. attached

INTERFERING SUBSTANCE(S):

STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:

PROBLEMS / PRECAUTIONS

- Special problems encountered:
- Precautions to be taken during
- analysis of samples:

- handling of samples:

- storage of samples:

TOTAL TIME FOR COMPLETION:

8.1.19. Instrument / detector for enforcement

Indicate the instrument / detector used in the enforcement method. If applicable, select "other:" and state "enforcement same as data collection method".

Copy this field if more than one method needs to be specified.

Give any further details in field "Details on data enforcement method".

8.1.20. Details on enforcement method

Briefly describe further details on the principles of the enforcement method if applicable (otherwise leave field empty). Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.

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 HPVC, Pesticides NAFTA or EU REACH) thereof. If further details are required, insert (sub)headings) as appropriate, e.g.:

INSTRUMENTATION

- Make(s)/model(s) of instrumentation used:

- Specificity of detector(s):

- Columns (packing material, size):

- Carrier gases: for GC:

- Operating procedures:

- Mobile phase for HPLC:

- Retention times for substance and standards:

CHROMATOGRAMS: see Fig. attached

INTERFERING SUBSTANCE(S):

STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:

PROBLEMS / PRECAUTIONS

- Special problems encountered:
- Precautions to be taken during
- analysis of samples:
- handling of samples:
- storage of samples:

TOTAL TIME FOR COMPLETION:

8.1.21. Instrument / detector for confirmatory method

Indicate the instrument / detector used in the confirmatory method (if any). If applicable, select "other:" and state "no confirmatory method used/required".

Copy this field if more than one method needs to be specified.

Give any further details in field "Details on data confirmatory method".

8.1.22. 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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

8.1.23. 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.

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.

8.1.24. Recovery results (data collection method)

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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

8.1.25. Characteristics for data collection method

For each compound (analyte) addressed (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:"), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio.

Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

8.1.26. Recovery results (enforcement method)

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. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

8.1.27. Characteristics for enforcement method

For each compound (analyte) addressed (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:"), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio.

Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field "Any other information on results incl. tables". Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. "... see Table 1").

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

8.1.28. Independent laboratory validation

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. Consult the programme-specific guidance (e.g. OECD HPV, Pesticides NAFTA or EU REACH) thereof.

8.1.29. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

8.1.30. 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.

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.

8.1.31. 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.

Tabella E.522. Field Descriptions

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.
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.

8.1.32. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

8.1.33. Conclusions

Enter any conclusions if applicable.

8.1.34. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

8.1.35. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9. [9] Residues in food and feedingstuffs

9.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

9.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

9.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

9.2. [9.1] Preliminary: Metabolism in livestock and crops

9.2.1. [9.1.1] Preliminary: Metabolism in livestock

No description yet available.

9.2.2. [9.1.2] Preliminary: Metabolism in crops

No description yet available.

9.2.3. [9.1.3] Preliminary: Metabolism in rotational crops

No description yet available.

9.3. [9.2] Preliminary: Residues in livestock and crops

9.3.1. [9.2.1] Preliminary: Residues in livestock

No description yet available.

9.3.2. [9.2.2] Preliminary: Residues in rotational crops

No description yet available.

9.4. [9.3] Migration of residues into and their behaviour on food or feedingstuffs

9.4.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

9.4.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

9.4.1.2. 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 information on migration into foodstuffs of the substance in contaminated food or feedingstuffs including the identification of residues and transformation products and/or the behaviour of the residues on food or feedingstuffs, if required so by the relevant legislation (e.g. EU BPD Ann. IIIA, XI.1.1, XI.1.2, XI.1.3, XI.1.5, XI.1.6).

9.4.1.3. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.523. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227

	Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

9.4.1.4. 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.

9.4.1.5. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

9.4.1.6. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9.4.1.7. Product type

Indicate the product type addressed by the information entered in this record. Leave field empty if not applicable.

9.4.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.524. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.);

	<ul style="list-style-type: none"> - To indicate if a 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.
Deviations from guideline (Deviations)	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.

9.4.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

9.4.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

9.4.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

9.4.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.525. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

9.4.1.13. Radiolabelling

Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field "Details on test material".

9.4.1.14. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

9.4.1.15. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available

- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

9.4.1.16. Details on properties of test surrogate or analogue material

ONLY if the study summary is a read-across to another substance, i.e. analogue or surrogate (e.g. degradation / transformation product), enter any relevant details on the physico-chemical or other relevant properties. Use freetext template and delete/add elements as appropriate.

Note that the physico-chemical properties of the substance for which the submission is made should be recorded in the corresponding chapters (templates) and therefore need not be repeated here. Nevertheless, the possible influence of any physico-chemical properties should be indicated / discussed in appropriate fields, particularly in fields "Details on test conditions" and "Details on results". This holds also true if any property of the substance is different in the test medium as compared to the data recorded in the section on physico-chemical properties, e.g. lower water solubility.

9.4.1.17. Further 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 (e.g. EU BPD TNsG).

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".

9.4.1.18. 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.

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.

9.4.1.19. Migration into food or feedingstuffs

Indicate the migration of the test substance into food or feedingstuffs for the test conditions indicated in the corresponding subfield. If test results differ, multiply this block of fields for the different test conditions and observations as applicable.

Tabella E.526. Field Descriptions

Test No.	Select a consecutive test number from drop-down list if more than one test runs are reported.
Test conditions	Briefly specify the relevant test conditions, e.g. contact time, concentration of substance.

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. For more detailed information or tables use fields "Details on results" or "Any other information on results incl. tables", respectively.
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9.4.1.20. 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".

9.4.1.21. Identity of degradation 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".

Tabella E.527. Field Descriptions

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.
Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" if identity according to a standard identifier is not known. Specify if another identifier is provided (e.g. "Other: xxx").
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

9.4.1.22. 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 "no data" as applicable.

9.4.1.23. 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 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 "Attached background material".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. EU BPD, OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

9.4.1.24. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

9.4.1.25. 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.

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.

9.4.1.26. 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.

Tabella E.528. Field Descriptions

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.
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.

9.4.1.27. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

9.4.1.28. Conclusions

Enter any conclusions if applicable.

9.4.1.29. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

9.4.1.30. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9.5. [9.4] Expected exposure and proposed acceptable residues

9.5.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

9.5.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

9.5.1.2. 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 information on expected exposure and/or proposed acceptable residues if required so by the relevant legislation. For instance, estimation of the exposure potential or actual exposure of the active substance to humans or animals through food and feedingstuffs and other means, proposed acceptable residues and the justification of their acceptability (e.g. EU BPD Ann. IIIA, XI.1.4; XI.1.7).

9.5.1.3. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.529. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.

Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

9.5.1.4. 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.

9.5.1.5. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

9.5.1.6. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9.5.1.7. Product type

Indicate the product type addressed by the information entered in this record. Leave field empty if not applicable.

9.5.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.530. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
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Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

9.5.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

9.5.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

9.5.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

9.5.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.531. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

9.5.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available

- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

9.5.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

9.5.1.15. Further details on study design

Describe the study design, i.e. methodology used to estimate the potential of exposure or determine actual exposure of the active substance to humans or animals through food and feedingstuffs and other means.

If proposed acceptable residues are recorded, describe the relevant input parameters and how these values were derived.

Consult any the programme-specific guidance (e.g. EU BPD TNsG).

9.5.1.16. 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.

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.

9.5.1.17. Details on results

Briefly summarise all relevant results, i.e. estimated potential or actual exposure of the active substance to humans or animals through food and feedingstuffs and other means, and/or proposed acceptable residues, including the justification of their acceptability.

As appropriate include table(s) with raw data in the rich text field "Any other information on results incl. tables".

Note: Specific tables may be required. Consult the programme-specific guidance (e.g. EU BPD TNsG).

9.5.1.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

9.5.1.19. 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.

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.

9.5.1.20. 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.

Tabella E.532. Field Descriptions

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.
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.

9.5.1.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

9.5.1.22. Conclusions

Enter any conclusions if applicable.

9.5.1.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

9.5.1.24. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9.6. [9.5] Additional information on residues in food and feedingstuffs

9.6.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

9.6.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

9.6.1.2. 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".

REMARKS ON PURPOSE OF THIS TEMPLATE:

This template can be used for summarising any other information related to residues on food and feedingstuffs and other means, for which no specific template is provided.

9.6.1.3. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.533. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.

Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

9.6.1.4. 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.

9.6.1.5. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

9.6.1.6. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

9.6.1.7. Product type

Indicate the product type addressed by the information entered in this record. Leave field empty if not applicable.

9.6.1.8. 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. US EPA in addition to OECD guideline).

Tabella E.534. Field Descriptions

Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - "no guideline followed" (if none of above qualifiers apply. If so, fill in field "Principles of method if other than guideline"); - "no guideline available" (if so, fill in field "Principles of method if other than guideline"). - "no guideline required" (if so, fill in field "Principles of method if other than guideline").
Guideline	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
Deviations from guideline (Deviations)	

	For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.
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9.6.1.9. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

9.6.1.10. GLP compliance

Indicate whether the study was conducted following Good Laboratory Practice or not. Select "yes (incl. certificate)" if a GLP certificate of a test facility is available. Select "yes" if a GLP compliance statement is available, but no information on a GLP certificate. 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.

9.6.1.11. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

9.6.1.12. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.535. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.

9.6.1.13. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable

- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

9.6.1.14. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available
- Isomers composition: specify if applicable

9.6.1.15. Details on study design

Describe the study design, i.e. methodology used.

9.6.1.16. 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.

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.

9.6.1.17. Details on results

Briefly summarise all relevant results. As appropriate include table(s) with raw data in the rich text field "Any other information on results incl. tables".

9.6.1.18. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

9.6.1.19. 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.

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.

9.6.1.20. 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.

Tabella E.536. Field Descriptions

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.
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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.
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9.6.1.21. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

9.6.1.22. Conclusions

Enter any conclusions if applicable.

9.6.1.23. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

9.6.1.24. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

10. [10] Effectiveness against target organisms

10.1. Endpoint summary record

In the following, the online help texts for all data entry fields provided with any Endpoint summary record for this IUCLID section are listed. As to whether and to what extent endpoint summaries should be prepared, refer to the relevant guidance for the respective chemical programme, e.g., the Technical Guidance Document (TGD) on preparing the Chemical Safety Report under REACH in its most recent version.

For technical guidance on how to manage Endpoint summary records, see How to manage Endpoint summary records in sections 4 - 10, respectively. For details on data types, see What data types are available for input fields and how are they used?.

10.1.1. Short description of key information

Enter a full short description of the most relevant endpoint data. This includes in principle the summary information that is compiled e.g. in the OECD Full SIDS Summary format or other endpoint summary formats. Provide only the most relevant details, which could be, depending on the cases, the test guideline used, test organism and exposure duration. Normally no reliability score needs to be indicated as it can be assumed that the studies identified are valid (reliability score 1 or 2). If this is not the case (for instance if the reliability of a published study cannot be assigned or if several less valid studies are used for a weight of evidence analysis), the reliability indicators should be specified.

Also several key studies can be referenced as applicable. However, the characterisation of the endpoint data should be kept as concise as possible. Examples of what could be entered here are as follows:

- Melting point: 54.6-55.8 °C at 1,013 hPa
- Water solubility: completely miscible
- pH: 6.9 (80 mg/l water) at 20°C (OECD TG105)
- Oxidation reduction potential: no data available
- Phototransformation in air: T1/2 = 9.32 x 10⁻² yr (sensitizer: OH radical) (AOP Win v 1.86)
- Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
- Short-term toxicity to fish:

LC50 (96h) < 100 mg/l for *Pimephales promelas* (OECD TG 203)

LC50 (48h) = 3.2 mg/l for *Oryzias latipes* (OECD TG 203)

- Acute toxicity:

Dermal: LD50: > 2,000 mg/kg for rat (limit test)

- Genetic toxicity:

In vitro:

Gene mutation (Bacterial reverse mutation assay / Ames test): *S. typhimurium* TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)

10.1.2. Discussion

In this rich text field, describe the assessment you have made for the given endpoint. Provide the rationale for the choice of the key study(ies) and the choice of the key parameter that, according to your judgement, characterise the endpoint. This includes a discussion of the key information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.

If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc.

10.2. [10.1] Effectiveness against target organisms and intended uses - general information

10.2.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

10.2.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

10.2.1.2. 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 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.

10.2.1.3. 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.

Tabella E.537. Field Descriptions

<p>Scientific name of target organism (Scientific name)</p>	<p>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.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. "I.1.1.1 (EU BPD)".</p>
<p>Common name of target organism (Common name)</p>	<p>Select appropriate common name from picklist. If not listed, select "other" and specify. If not given/known, select "no data". See also instructions on this block of fields.</p> <p>Any remarks can be entered in the supplementary remarks field.</p>
<p>Developmental stage of target organism (Developm. stage)</p>	<p>Indicate the developmental stage of the target organism. If not listed, select "other" and specify. If not given/known, select "no data". If not applicable, leave field empty.</p>

	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, e.g. "I.1.1.1 (EU BPD)".
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10.2.1.4. 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.

10.2.1.5. Function addressed

Indicate the function of the substance. You can copy this field 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, e.g. "III.1.1 (EU BPD)".

10.2.1.6. 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.

10.2.1.7. Field of use envisaged / User

In addition to the product type indicated, further information on the envisaged use may be required according to the relevant guidance document (e.g. EU BPD TNsG). This can include a detailed description of the overall use pattern, indication of any relations which give case to exposure, hazard classes, or specific environments in which the product will be used.

Note: If the information or part of the information required by the legislation is included in another chapter, it is sufficient to include a cross-reference to that chapter / record. For instance, state "Overall use pattern described in chapter 2.5."

10.2.1.8. Method of application

For the product, indicate the method of application. You can copy this field as appropriate for indicating more than one method. If not listed, select "other" and specify.

Any remarks can be entered in the supplementary remarks field, for instance any code for the method of application if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. "VII.1 (EU BPD)".

10.2.1.9. Details on application

For the product, provide further details on the method of application if required so according to the instructions given in the relevant guidance documents (e.g. EU BPD TNsG). Outline the descriptions using the freetext template as appropriate (delete/add elements). You may summarise data on application and geographical or climatic variations in tabular form. 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").

Note: If the information or part of the information required by the legislation is provided in another section, it is sufficient to include a cross-reference to that section / record.

Explanations:

- DESCRIPTION OF APPLICATION SYSTEM USED: Give name of substances used for dilution including their concentration in the biocidal product. State any other substance(s) added including purpose and concentration in the product. Describe the application technique(s). Particularly if more than one product type or application method is applicable, you may summarize these data in tabular form.

- APPLICATION RATE: For each product type and application technique give the recommended dose of the biocidal product and the active substance per object (e.g. per surface area of the material to be protected or as a concentration in a water system). Refer to the instructions given in the relevant guidance documents (e.g. EU BPD TNsG).

- LIKELY / FINAL CONCENTRATION AT WHICH ACTIVE SUBSTANCE OR PRODUCT WILL BE USED: self-explanatory

- NUMBER AND TIMING OF APPLICATIONS: Indicate the recommended number and timing, i.e. duration of application and possible reapplications as well as waiting periods considered necessary. Particularly if more than one product type or application method is applicable, you may summarize these data in tabular form.

- GEOGRAPHICAL VARIATIONS: Where relevant, describe how the application should be varied in different parts of the Community.

- CLIMATIC VARIATIONS: Where relevant, describe how the application should be varied at different climatic conditions.

- WAITING PERIODS TO PROTECT MAN AND ANIMALS: Where relevant, specify any waiting periods.

10.2.1.10. 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 (e.g. EU BPD TNsG).

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".

10.2.1.11. 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, e.g. "III.1.2 (EU BPD)".

10.2.1.12. 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 (e.g. EU BPD TNsG).

10.2.1.13. (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.

10.2.1.14. Management strategies to avoid resistance

Describe any appropriate management strategies towards the minimization of the development of resistance.

10.2.1.15. Any other known limitations and management strategies

As applicable describe any other known limitations and relevant management strategies towards them.

10.2.1.16. 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.

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.

10.2.1.17. 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.

Tabella E.538. Field Descriptions

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.
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.

10.2.1.18. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

10.2.1.19. Conclusions

Enter any conclusions if applicable.

10.2.1.20. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

10.2.1.21. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

10.3. [10.2] Efficacy data

10.3.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

10.3.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

10.3.1.2. 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 relevant information on the test substance in fields on "Test materials".

PURPOSE OF THIS TEMPLATE:

This template can be used for summarising an efficacy study or, if appropriate and in line with relevant legislation guidance, several efficacy studies, conducted to support any proposed label claim.

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 in a study summary or whether several studies can be summarised in one record.

If this template is used to summarise several efficacy studies, the following should be taken into account:

- Attach summary table(s) in an appropriate rich text area, e.g. field "Any other information on results incl. tables" and/or attach graphs in field "Attached background material".

- Tests summarised in overview table(s) should have some common objectives and conditions as far as possible. For instance, summarise all laboratory studies in one record that are intended to support a specific label claim, while combining all field studies in another record. Likewise you may use other criteria for splitting up into more than one record.
- If possible fill in distinct fields with information that relates to all studies summarised in a given record. For instance, enter fields "Function addressed", "Objective / label claim(s)" addressed".
- Leave those fields or field blocks empty that are intended mainly for reporting an individual study, such as "Reference", "Test guideline", "Principles of method if other than guideline", fields under heading "Test materials". Provide this type of information in the tables.
- It may be useful to indicate that there are studies for which data protection is claimed. If so you can indicate so in the corresponding field and include a note, in the supplementary remarks field, referring to the results table in which the respective study or studies is/are indicated as being data protected.

10.3.1.3. Objective / label claim(s) addressed

Briefly describe the objective of the efficacy data summarised in this record. This will normally be a (draft) label or statements concerning the label claim that is addressed or supported. As appropriate, include relevant label information such as function, mode of action, target / pest organism(s), stage of pest targeted, area of use, application methods and rates at which the product is to be applied.

If a label addresses multiple product types, functions, target organisms, materials or organisms to be protected, it may be sensible or required according to legislation-specific guidance to use separate records for each of them, as an alternative option to addressing all label claims by efficacy data in one record. One approach could be to create separate records for the label items taken line by line, or point by point (possibly in another order), and include the corresponding efficacy data intended to support this/these label claim(s). Make sure that every part of each claim and recommendation of the label has been covered.

10.3.1.4. Source of information / type of study(ies)

Indicate whether the information entered originates from "public domain evidence" (i.e. suitable information in published papers and books), "summary of preliminary tests" (including early screening studies) or "summary information" (e.g. overview of several tests) or addresses a "laboratory study", "simulated use test / small scale trials", "field study / operational trials" or other (to be specified). If the information was extrapolated from study(ies) with closely related formulations, select the corresponding indicator from the picklist.

This field is repeatable. As appropriate, copy the field e.g. for indicating "summary information" and "simulated test data".

In the supplementary remarks field, you can add explanations as appropriate.

Note: In field "Study result type", option "experimental result" should also be selected if the efficacy data recorded is extrapolated information from experimental study(ies) with another target or related formulation.

10.3.1.5. Reference

Indicate the bibliographic reference of the study report or publication the study summary is based on. Always enter the primary reference in the first block of fields (i.e. Sort no. = 1), 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.

Tabella E.539. Field Descriptions

Reference type	Indicate the type of reference, e.g. "Study report" or "Publication". Select "Other company data" to characterise any unpublished information from a company other than a study report. Select "Grey literature" for any other unpublished information or "other:" and specify.
Author(s) (or transferred reference) (Author)	For ease of sorting and searchability use following convention: Surname, Initial (Example 1: White D, Ruehl KJ, Borman SA & Little J. Example 2: Hartley M & Murray W (avoid unnecessary full-stops, commas)). If no individuals are cited as authors, enter name of company or organisation or "Anon." as appropriate. Note that the complete bibliographic reference may appear in this field after migration of unstructured data from existing databases.
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field "Report date".
Title	Include the title of the report. For publications, include the title of the article of a journal or article/chapter of a book (e.g. handbook).
Bibliographic source	Not relevant for any study report. For publications or any other literature source (grey literature) specify the following type of information: (i) Title of scientific journal or book (e.g. if handbook); (ii) Volume of journal; (iii) Editor, publisher, place of publication for books or articles in books; (iv) Pagination. Example 1 (journal): J. Agric. Food Chem. 38: 215-227 Example 2 (handbook): In: Lyman WJ (ed.) Handbook of chemical property estimation methods. Environmental behavior of organic compounds. McGraw-Hill Book Company 15.1-15.34, New York.
Testing laboratory	Either manually enter the name of the testing laboratory or select it from the picklist. In either case, editing is possible.
Report no.	Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
Owner company	

	Either manually enter the identity of the company who owns the data or select it from the picklist. In either case, editing is possible.
Company study no.	Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
Report date	Specify the complete date of the study report, e.g. "2005-05-12" for 12 May 2005. Note that subfield "Year" should be completed in any case for sorting and searching purposes.

10.3.1.6. 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.

10.3.1.7. 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 (e.g. with vertebrates).

In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. "for justification see attached document X")

10.3.1.8. Cross-reference to same study

A cross-reference can be included to indicate that the same study is recorded in another record. Indicate the respective chapter and record ID and enter relevant explanatory text. This may be useful if specific endpoints of a given study are described in another chapter (e.g. results on reproduction toxicity in case of a combined repeated dose / reproduction toxicity study) or if more than one experiment is described by the same study report, but included in separate records.

Check with the relevant guidance document whether all the methodology details must be repeated or whether a cross-reference to the same study in another chapter may suffice.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

10.3.1.9. 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. US EPA in addition to OECD guideline).

Tabella E.540. Field Descriptions

<p>Qualifier</p>	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - "according to" (if a given test guideline was followed); - "equivalent or similar to" (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").
<p>Guideline</p>	<p>Select the applicable test guideline, e.g. "OECD Guideline xxx". If the test guideline used is not listed, choose "other guideline:" and specify the test guideline in the related text field.</p> <p>In this text field, you can also enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline.); - To indicate if a 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.
<p>Deviations from guideline (Deviations)</p>	<p>For robust study summaries or as requested by the regulatory programme, indicate if there are any deviations from the test guideline specified. If "yes" is selected, only briefly state relevant deviations in the supplementary remarks field (e.g. "other species used"); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>

10.3.1.10. 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. 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.

If an estimation method was used (to be indicated in field "Test result type") state the equation(s) and/or computer software or other methods applied to calculate the value(s).

10.3.1.11. Compliance with quality standards

Indicate whether the efficiency data were generated according to GEP (Good Experimental Practice) or by an officially recognised organisation. If neither or is 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".

10.3.1.12. Test material equivalent to submission substance identity

Indicate if the test material used in the study is equivalent to the submission substance identity. If "yes" is selected, the corresponding identity is automatically entered in the subsequent block of fields "Test material identity".

If "no" is selected, identify the test material in the subsequent block of fields "Test material identity". In this case, also make sure that the information entered in field "Study result type" is consistent, i.e. "read-across from supporting substance (structural analogue or surrogate)".

NOTE: If a completed record is used for another submission, you may have to update both fields "Study result type" and "Test material equivalent to submission substance identity".

10.3.1.13. Test material identity

If the identity of the test material used for this study is not included in this block of fields automatically, indicate the identity for one or more appropriate identifiers, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields as appropriate.

If another than the submission substance identity was selected erroneously, go back to field "Test material equivalent to submission substance identity" and select "yes". This will prompt automatic entry of the respective identifiers.

Tabella E.541. Field Descriptions

Identifier	Select an appropriate identifier from drop-down list, e.g. "CAS number". Use "Other:" and specify, if identity according to a standard identifier is not known or if an additional chemical name or number is provided.
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Identity	Select the corresponding substance identity from drop-down list or enter manually if the identity is not available from the list or if no list is provided for the type of identifier selected.
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10.3.1.14. 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 so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. "VIII.1 (EU BPD)".

10.3.1.15. Details on test material

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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Note that any information that can be claimed confidential should be included in the subsequent field "Confidential details on test material".

Explanations:

- Name of test material (as cited in study report): only if different from any other identifiers provided in the preceding fields.
- Molecular formula (if other than submission substance): specify
- Molecular weight (if other than submission substance): specify
- Smiles notation (if other than submission substance): provide if available
- InChI (if other than submission substance): provide if available
- Structural formula attached as image file (if other than submission substance): see Fig.: only if different from submission substance. Indicate Fig. no. if a file is attached in field "Attached document", e.g. state "see Fig. 1".
- Substance type: indicate whether pure active substance, technical product, formulation or other.
- Physical state: indicate "gas", "solid" or "liquid" only if different from submission substance or if substance can occur in different physical states.
- Analytical purity: specify in %
- Impurities (identity and concentrations): specify

- Composition of the test material, percentage of components: specify if applicable
- Isomers composition: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: provide if available
- Expiration date of the lot/batch: provide if available
- Radiochemical purity (if radiolabelling): specify if applicable
- Specific activity (if radiolabelling): specify if applicable
- Locations of the label (if radiolabelling): specify if applicable
- Expiration date of radiochemical substance (if radiolabelling): specify if applicable
- Storage condition of test substance: specify if applicable
- Stability under test conditions: indicate if available

10.3.1.16. Confidential details on test material

Enter any confidential information on the test material in this separate field. 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 HPVC, Pesticides NAFTA or EU REACH) thereof.

Explanations:

- Analytical purity: specify in %
- Impurities (identity and concentrations): specify
- Composition of the test material, percentage of components: specify if applicable
- Purity test date: provide if available
- Lot/batch No.: : provide if available
- Expiration date of the lot/batch: : provide if available

- Isomers composition: specify if applicable

10.3.1.17. Analytical monitoring

Indicate whether the active substance was monitored during the test.

10.3.1.18. 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.

10.3.1.19. 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.

Tabella E.542. Field Descriptions

Scientific name of target organism (Scientific name)	<p>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.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. "I.1.1.1 (EU BPD)".</p>
Common name of target organism (Common name)	<p>Select appropriate common name from picklist. If not listed, select "other" and specify. If not given/known, select "no data". See also instructions on this block of fields.</p> <p>Any remarks can be entered in the supplementary remarks field.</p>
Developmental stage of target organism (Developm. stage)	<p>Indicate the developmental stage of the target organism. If not listed, select "other" and specify. If not given/known, select "no data". If not applicable, leave field empty.</p>

	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, e.g. "I.1.1.1 (EU BPD)".
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10.3.1.20. Details on test/target organisms

Provide further details on test organisms, particularly on rearing conditions, numbers and sexes used (where appropriate) and any other relevant information. Because of the wide range of efficacy trials identification of all relevant items is not practical. Hence, the optional freetext templates provided are not exhaustive. If you use one of them, delete/add elements and edit text set in [...] as appropriate. Specific studies may require other or additional information to be included. 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. EU BPD (TNsG)) thereof.

If this record summarises several studies with different organisms, it may be appropriate to include the most relevant details in the summary table(s).

10.3.1.21. 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, e.g. human, pets, farm animals, fur- and wool-bearing animals, drinking water, hard surface material, porous surface.

Note: If studies were conducted on human beings (e.g. testing insect repellents for human skin), it should be indicated whether and what kind of consent was received from the persons studied.

10.3.1.22. Total exposure duration (contact time)

Include numeric value or range (if several test runs or trials) and unit of duration in the respective subfields.

Tabella E.543. Field Descriptions

Exposure duration (Duration)	<p>Enter a numeric value or a range of numeric values according to following conventions:</p> <p>(i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by ">", ">=" or "ca." (e.g. "20", "ca. 20", ">20").</p> <p>(ii) In the second numeric field, enter a single value if preceded by "<" or "<=".</p> <p>(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").</p>
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Unit (no label)	Select from drop-down list.
Remarks	Enter any remarks related to the total exposure duration.

10.3.1.23. Mode of efficacy assessment

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 or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. EU BPD) thereof.

10.3.1.24. 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, for instance any code for the method of application if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. "VII.1 (EU BPD)".

10.3.1.25. Details on study design

Provide further details on the study design. Because of the wide range of efficacy trials, identification of all relevant items is not practical. Hence, the optional freetext templates provided are not exhaustive. If you use one of them, delete/add elements and edit items as appropriate. Specific studies may require other or additional information to be included. 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. EU BPD) thereof.

If this record summarises several studies, it may be appropriate to include the most relevant details in the summary table(s).

10.3.1.26. 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.

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.

10.3.1.27. 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.

Tabella E.544. Field Descriptions

Efficacy parameter	Indicate the efficacy / performance parameter (e.g. % kill/cidal activity) to which the index entered in the next field refers to.
Efficacy (in %)	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. "20", "ca. 20", ">20"). (ii) In the second numeric field, enter a single value if preceded by "<" or "<=". (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. "2 - 8" or ">2 <8").
Time to produce effect	Select from drop-down list.
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.
Interfering substances	Indicate if interfering substances were present. If "yes" is selected, briefly specify in the supplementary remarks field.
Remarks	Enter any remarks related to the efficacy / performance assessment recorded in this block of fields.

10.3.1.28. 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.

Tabella E.545. Field Descriptions

Minimum effective dose (Min. effective dose)	Enter numeric value of minimum effective dose.
Unit of minimum effective dose (no label)	Select from drop-down list.

Time to produce effect	Select from drop-down list.
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.
Interfering substances	Indicate if interfering substances were present. If "yes" is selected, briefly specify in the supplementary remarks field.
Remarks	Enter any remarks related to the minimum effective dose recorded in this block of fields.

10.3.1.29. Details on results

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.

10.3.1.30. 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.

10.3.1.31. 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.

10.3.1.32. Undesirable or unintended side effects

Indicate whether any undesirable or unintended side effects were observed or not. In below field "Details on undesirable or unintended side effects", give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible.

Select "not examined" or "no data" as applicable.

10.3.1.33. 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 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:

10.3.1.34. 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.

10.3.1.35. 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 bridging arguments.

Use freetext template and delete/add elements as appropriate.

10.3.1.36. Remarks on results including tables and figures

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: Both the "Materials and methods" section and "Results" section. In addition the fields "Overall remarks" and "Executive summary" allow rich text entry.

10.3.1.37. 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.

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.

10.3.1.38. 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.

Tabella E.546. Field Descriptions

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.
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.

10.3.1.39. Attached full study report

If required, an electronic copy of the full study report can be attached as WORD, pdf or other document type, which will not be integrated in any report, but must be handled as separate files.

Note: In the export administration you can indicate whether the attached files should be included in the data export or not.

10.3.1.40. Conclusions

Enter any conclusions if applicable.

10.3.1.41. Executive summary

If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective freetext template if available from the drop-down list or copy it from the corresponding document.

Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.

10.3.1.42. Cross-reference to other study

A Cross-reference to other study or other studies can be included which are considered relevant in the interpretation of the test results, e.g. for supporting the conclusion that an effect observed was not substance-related. Indicate the respective chapter(s) and record ID(s) and enter relevant explanatory text.

Such cross-references may be useful if it is considered relevant to discuss other results at the summary level of a single study. It should be noted that the overall appraisal of results from different studies is normally done in the hazard or risk assessment.

Note that any such cross-reference may become useless if a record is either printed or exchanged on its own.

11. [11] Guidance on safe use

11.1. Endpoint study record

In the following, the online help texts for all data entry fields provided with any Endpoint study record for this IUCLID section are listed. For sections 4 to 10, these guidance notes are completely based on the so-called OECD Harmonised Templates (see Rationale behind IUCLID Endpoint Study Records - OECD harmonised templates in chapter chapter D.4.7.1 What is an Endpoint study record?)

IUCLID per se does not prescribe how detailed the study summaries should be recorded. Refer to the relevant guidance for the respective chemical regulatory programme thereof.

For technical guidance on how to manage Endpoint study records, see chapter D.4.7 How to manage Endpoint study records in sections 4 - 13. For details on data types, see chapter D.4.5 What data types are available for input fields and how are they used?

11.1.1. Administrative data

Under this main heading, fields are subsumed for identifying the purpose of the record (e.g., "key study"), the type of result (e.g., "experimental study"), data waiving indication (if any), reliability indication, and flags for indicating the regulatory purpose envisaged and/or any confidentiality restrictions. This kind of data characterise the relevance of a study summary and are therefore displayed on top of each Endpoint Study Record. For detailed guidance, refer to chapter D.4.7.7.1 Administrative data.

11.1.2. UN number

United Nations (UN) Numbers are four-digit numbers used in international transportation to identify hazardous chemicals or hazardous materials.

11.1.3. Class

Indicate the class or division

11.1.4. Classification code

Indicate the classification code

11.1.5. Packaging group

Indicate the packaging group

11.1.6. Labels

Indicate the labels

11.1.7. UN number

United Nations (UN) Numbers are four-digit numbers used in international transportation to identify hazardous chemicals or hazardous materials.

11.1.8. Class

Indicate the class or division

11.1.9. Classification code

Indicate the classification code

11.1.10. Packaging group

Indicate the packaging group

11.1.11. Labels

Indicate the labels

11.1.12. Remarks

Add any additional remarks

11.1.13. UN number

United Nations (UN) Numbers are four-digit numbers used in international transportation to identify hazardous chemicals or hazardous materials.

11.1.14. Proper shipping name and description

Indicate the proper shipping name, including the description.

11.1.15. Chemical name

Only indicate the chemical name if it differs from the proper shipping name (in case of \"n.o.s\")

11.1.16. Class

Indicate the class or division

11.1.17. Packaging group

Indicate the packaging group

11.1.18. EmS number

Indicate the EmS number: Emergency Procedures for Ships Carrying Dangerous Goods

11.1.19. Labels

Indicate the labels

11.1.20. Marine pollutant

If the transported substance or goods are defined as harmful to the marine environment this has to be identified as a marine pollutant or a severe marine pollutant by the letters P or PP.

11.1.21. Remarks

Add any additional remarks

11.1.22. UN number

United Nations (UN) Numbers are four-digit numbers used in international transportation to identify hazardous chemicals or hazardous materials.

11.1.23. Proper shipping name and description

Indicate the proper shipping name, including the description.

11.1.24. Chemical name

Only indicate the chemical name if it differs from the proper shipping name (in case of \"n.o.s\")

11.1.25. Class

Indicate the class or division

11.1.26. Packaging group

Indicate the packaging group

11.1.27. Labels

Indicate the labels

11.1.28. Remarks

Add any additional remarks

11.1.29. Additional transport information

Add any additional remarks

12. [12] Literature search

This section can be used to record any literature search(es) carried out. Specify the date of the literature search in field `Date` (only format yyyy-MM-dd allowed, e.g. 2007-03-20). In field `Remarks`, describe the databases searched and the main search profile. Indicate the major search results, e.g. state for which endpoints no information could be retrieved. It is also possible to attach the document with the search profile in tab **Attachments** (right-click into the left pane and then click the **Add** button).

13. [13] Assessment Reports

This section serves as a container to attach any Assessment Report(s), e.g. a chemical safety report in the context of REACH or an OECD SIDS Initial assessment report (SIAR). This allows submitting the technical dossier and the assessment report in one single package.

Concise Assessment Reports could be inserted in the rich text area `Discussion` by copy and paste operation. However, since the capacity of this field is limited, more comprehensive documents should be attached in field `Document` (click the paperclip and then the **Add** button).

In field `Type of report`, select the respective type from the picklist (e.g. REACH Chemical safety report (CSR)). If the report type is not listed, select "other:" and specify. Any remarks can be given in the field `Remarks`.

As in any record, flags indicating confidentiality and/or restriction to specific regulatory purpose can be set in the dialogue for Administrative Data.