

# IUCLID 5

## Guidance and Support

### CSR Tool Plugin for IUCLID5.3 User Manual (with annotated CSR template)

**IUCLID 5**  
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

April 2011  
version 3.0



IUCLID 5 has been developed by the European Commission  
in association with the OECD

## PREFACE

The aim of this guidance document is to provide insight into what kind of information the Chemical Safety Report (CSR) generator plugin (CSR plugin) captures from IUCLID 5 records and the principle rules underlying the automatic generation of a CSR rtf document, which may serve as starter for the CSR.

This guide also provides hints and tips on how to optimise data entry in the IUCLID 5 source records in such a way that any manual revision work is limited to a minimum.

## ORGANISATION OF THIS GUIDANCE DOCUMENT

This document is organised into the following two main parts:

- **Part 0: Overview of the most relevant changes in this version:**  
Describes the major changes made in the format and rules underlying the CSR plugin and improvements in the layout.
- **Part I: Principles of CSR generation**  
Describes the general rules and format underlying the generation of a CSR template using the CSR plugin including examples and practical hints.
- **Part II: Annotated CSR Template**  
Provides a sample CSR Template, filled with the labels or descriptions of the relevant IUCLID 5 source fields instead of real data including annotations on specific rules where appropriate.

## DOCUMENT HISTORY

Version	Changes
2.2	Addition of "Changes in CSR Plugin Version 5.2.6" to "Part 0: Overview of the most relevant changes in this version".
	Addition of Note in section "3.1.2 Document file format" on possible incompatibility problems when using other than Microsoft Word/Microsoft Office versions.
2.1	3.1.3 Table of contents and list of tables: Guidance has been expanded.
	PART II: ANNOTATED CSR TEMPLATE: 1.3. Physico-chemical properties: Table 5. Overview of physico-chemical properties: <ul style="list-style-type: none"> <li>○ Title of 2nd column changed from "Value" to "Results"</li> <li>○ Title of 3rd column changed from "Remarks" to "Value used for CSA / Discussion"</li> <li>○ Specification for the item "Physical state at 20°C and 1013 hPa" updated according to modified rules.</li> </ul>
2.0	Addition of Part 0: Overview of the most relevant changes in this version. Adaptation of Parts I and II to changes described in Part 0.

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## PART 0: OVERVIEW OF THE MOST RELEVANT CHANGES IN THE CSR PLUGIN VERSION FOR IUCLID 5.3

Below the major changes made in the format and rules underlying the CSR plugin are documented.

### Changes in CSR Plugin Version 5.3.0

1. Adaptation to IUCLID 5.3

### Changes in CSR Plugin Version 5.2.6

1. Version 5.2.6 includes technical improvements and minor changes of the specifications including changes in versions 5.2.2 to 5.2.5, which were not published.
2. **CSR sections 6.1, 6.2, 6.3:**
  - The placeholders for the fields "Any other information on results incl. tables", which had been removed in version 5.2.0 to avoid insertion of lengthy rich text in CSR tables, have been put back. Nevertheless it is recommended to use either the relevant supplementary remarks fields or the field "Remarks" in the "Remarks and discussion" part.
  - All "Remarks" fields are now addressed (Note: The "Remarks" field from IUCLID section "4.11 Flash point" is not transferred yet by the CSR generator v. 5.2.5 released with Chesar v. 1.1). In section 4.14 free text can be entered in supplementary remarks fields when selecting any value in the related list field, e.g. "not determined" in field "Explosive (not specified)".
  - The restriction has been cancelled to transfer only records from IUCLID section "4.11 Flash point" if a concrete flash point is provided.
3. **Bug fixing: Endpoint summaries:**

In a few endpoint summaries (e.g. Vapour pressure) the field "Value used for CSA" was not captured if the "Temperature" field was blank.
4. **Improvement of layout:**

Table headings are now coloured and repeated on subsequent pages.

### Changes in CSR Plugin Version 5.2.1

1. **Bug fixing:** Endpoint study records from IUCLID section 7.8.1 "Toxicity to reproduction" with Data waiving information were not transferred correctly to the CSR.
2. **CSR section 1.3. Physico-chemical properties: Table "Overview of physico-chemical properties":** Rules have been added to ensure that for the item "Physical state at 20°C and 1013 hPa" the relevant data are captured either from the IUCLID endpoint summary 4.1 or, if not available, from the endpoint study record(s) in that section.

### Changes in CSR Plugin Version 5.2.0

#### Overview of the most relevant changes:

1. **Adaptation to IUCLID version 5.2:** The specifications of the CSR plugin were adopted to any CSR-relevant changes made in the IUCLID version 5.2 compared to version 5.1.
2. **Bug fixing:** Some bugs in the rules of the first version of the CSR plugin were fixed and some rules improved independently of the new IUCLID version. The bugs reported included:
  - a. Data waiver for autoflammability showed up in the CSR with wrong heading "Melting point".
  - b. IUCLID section 2.2 (DSD-DPD): Entries with Status = "other:" were not always transferred to the CSR section "3.3 Other classifications".
  - c. An UNDEFINED Error message occurred in the CSR if field "Study result type" = "QSAR" or "estimated by calculation" in IUCLID sec. 7.4.1.
  - d. Transfer of endpoint study records from IUCLID section 7.10 failed under some conditions.

3. **Chapter 2 MANUFACTURE AND USES**, new table under subheading "Quantities" reflecting the changes in IUCLID 5.2 section 3.2.
4. **Chapter 2.2 Identified uses**: New tables reflecting the changes in IUCLID 5.2 section 3.5.
5. **Chapter 2.3 Uses advised against**: New tables reflecting the changes in IUCLID 5.2 section 3.6.
6. **Chapter 3.1 Classification and labelling according to CLP / GHS**:
  - e. New chapter inserted.
  - f. New rule for "Related composition: <Related composition>"

7. **Endpoint study records in CSR chapters 4 - 7: Test material identity in column "Remarks" of overview tables**:

Comprehensive conditions and rules have been implemented for ensuring that the test material identity of each captured endpoint study record is analysed, i.e. compared with the identity of the Reference substance in IUCLID section 1.1. The outcome and further criteria trigger the printing of either the test material identity or a warning message.

The following peculiarities of IUCLID 5.2 and the Technical Completeness Check (TCC) have been taken into account:

- The fields "Test material equivalent to submission substance identity" (in IUCLID 5.2 renamed to "Identity of test material same as for substance defined in section 1 (if not read-across)") and "Test material identity" are not filled in automatically anymore, when a record is created.
- According to the ECHA Submission Manual #5, no identity must be given in the fields "Test material identity", if the field "Identity of test material same as for substance defined in section 1 (if not read-across)" is populated with "yes", except for referenced records. Since the latter cannot be edited once pasted in the target dataset, it cannot be excluded that the value entered in this field in the source dataset (i.e. "yes" or "no") gives a wrong meaning in the target dataset.

See the Appendix at the end of this overview for details on how the test material identity is handled by the plugin.

8. **Endpoint study records in CSR chapters 4 - 7: The rules for selecting endpoint study records to be inserted in overview tables has been updated based on the following rationale**:
  - g. In IUCLID 5.2, the new phrase "disregarded study" has been added to the picklist in the field "Purpose flag" allowing to explicitly indicate that a study is not used as key study although showing critical results. In the first version of the CSR plugin, such studies were identified based on the workaround "checkbox 'robust study summary' selected AND field 'Purpose flag' empty". This workaround created some confusion, as some records were flagged as 'robust study summary', but not with the intention to flag them as "disregarded study".

In the updated CSR plugin this workaround has been abandoned. Instead, the default text "disregarded study" is only printed if this phrase has been selected in the field "Purpose flag".
  - h. The selection criterion "field "Author" is not blank" has been abandoned. That is, any record with an entry in the "Purpose flag" is transferred to the relevant overview table. This gives the user a chance to identify those records where the relevant bibliographic information is missing.
  - i. The action rule that controls the output of the citation in the overview tables (Author + Year) and list of references (full citation) has been extended in such a way that either of the following default texts is inserted in case of missing information, if applicable:
    - >>>Author missing<<<;
    - >>>Author + Year missing<<<.In both cases these default texts are printed in the list of references, together with the full reference information.

9. **Overview tables, column "Results"**:

A placeholder for "Remarks" has been added to a number of repeatable Results blocks (where

newly introduced in IUCLID 5.2). This new field allows to provide at least some textual description of the results, if the distinct (i.e. list or numeric) fields cannot be filled in. Otherwise the Results column in the CSR table would be empty.

**10. Endpoint summaries:**

All changes made in IUCLID 5.2 in the endpoint summaries have been implemented.

**11. CSR section 5. HUMAN HEALTH HAZARD ASSESSMENT**, subsections 5.8.1.1, 5.8.1.2, 5.8.1.3, 5.8.1.4, 5.9.1.1, 5.9.2.1, 5.10.1.1, 5.10.1.2, 5.10.1.3:

Rules and format for "**estimated data**" have been made consistent with the other Human Health sections.

**12. CSR section 5 and subsections: Information from endpoint summary 7.10 Exposure related observations in humans:**

- j. A new subsection "Summary and discussion of human information" has been added after the main chapter heading 5. HUMAN HEALTH HAZARD ASSESSMENT matching the field "Discussion" of the endpoint summary 7.10.
- k. CSR section 5.1 - 5.10, subsections "Summary and discussion": New subheading "Summary and discussion of human information" and default text added after "Value used for CSA": *See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)*

(Note: Since there is only one Endpoint summary for the entire IUCLID section 7.10 "Exposure related observations in humans", such information cannot be automatically allocated to specific endpoints in the CSR. However, the above default text is only printed in a given CSR section, if (i) an endpoint summary for section 7.10 and (ii) at least one endpoint study record is available in the overview table on exposure-related observations in humans (indirect evidence that these studies are discussed in the Endpoint summary 7.10). Records in which the field "Endpoint addressed" is blank, cannot be allocated.)

**13. CSR section 5.10.2 Human information:**

In the first version of the CSR plugin, endpoint study records from IUCLID sections 7.10.1 / 7.10.2 / 7.10.3 / 7.10.5 with field "Endpoint addressed" = "neurotoxicity" or "immunotoxicity" were transferred to the table "Overview of exposure-related observations on neurotoxicity and/or immunotoxicity". Records field "Endpoint addressed" = "not applicable" or empty were ignored.

In the updated version all records with a Purpose flag are captured and transferred to three separate tables, i.e.

- Table: Overview of exposure-related observations on neurotoxicity
- Table: Overview of exposure-related observations on immunotoxicity
- Table: Overview of exposure-related observations: endpoint not specified

**14. CSR section 5.11.1 Overview of typical dose descriptors for all endpoints:**

The format for this table has been changed and rules have been implemented so that it is now automatically filled in provided that the relevant IUCLID data are available.

**15. Previous CSR section 5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation), application of assessment factors and derivation of the endpoint specific DN(M)EL:**

This section has been abandoned. Instead the updated table of the former section 5.11.3, now section 5.11.2, combines the information of both sections in one (see next point).

**16. CSR section 5.11.2 (formerly 5.11.3) Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects:**

The format for this table has been changed and rules have been implemented so that it is now automatically filled in, provided that the relevant IUCLID data are available. The (corrected) dose descriptor starting points are automatically calculated by multiplying the values of the fields "D(N)MEL" and "AF" provided in the Endpoint summary of IUCLID section 7. Toxicological information.

**17. CSR sections 6.1, 6.2, 6.3: "Classification according to GHS" added.**

**18. Data waiving records:**

The rules for capturing data waiving records have been adjusted as follows in order to be consistent with the TCC tool:

- l. If field "Purpose flag" is populated, the relevant information is transferred to the endpoint relevant part, i.e. overview table (regardless of whether field "Data waiving" is populated or not).
- m. If field "Purpose flag" is empty and field "Data waiving" is populated, the information from the fields "Data waiving" and "Justification for data waiving" is transferred to the data waiving part.
- n. Note: This approach reflects the TCC and the Data Submission Manual #5 (version 2.3, March 2010, chapter 4.4.3) according to which "*an individual Data waiving record should stand alone and not be mixed with other data such as existing study summaries*". Thus, data waiving information is only captured and transferred to the relevant part in the CSR if these rules are followed. In this respect, the CSR plugin may help identifying inappropriate records and improving them so that they pass the TCC.

**Improvement of layout****19. Header / footer of rtf document:**

In addition to the EC number and CAS number the chemical name captured from IUCLID section 1.1 "Identification" has been added in the header to account for cases where standard identifiers are not available.

**20. Table of Contents / List of Tables:**

In the first version of the CSR plugin, no predefined heading styles were applied to the Table of Contents and List of Tables generated by the plugin. Hence, updating these lists was not straightforward using a workaround described in the User Manual.

In the new version, predefined styles are applied to headings and table titles (e.g Heading 1; Table Heading) and the Word field code for TOC (Table of Contents) is inserted by the CSR plugin. These tables of contents can now be updated by pressing CTRL+a and then the F9 key, as instructed in the CSR document when it is created.

Note: In practice, deleting or adding any headings should normally not occur, because the format of the CSR is a standard format. However, it may be necessary to add or delete tables manually. In such case, it is recommended to copy and paste an existing paragraph with table number and title and update the title as appropriate. The table number is updated automatically on pressing CTRL+a and then the F9 key.

**21. Rich text areas:**

In the first version of the CSR plugin, any formatting used in rich text fields such as bold and underline and any tables got lost. Only plain text was transferred and inserted in the CSR document.

In the updated version, the most important formats are kept, including any tables.

**22. Landscape format:**

The new CSR plugin now features also the landscape format of tables where appropriate.

# PART I: PRINCIPLES OF CSR GENERATION

## 1. General Introduction

### 1.1. CSR requirements under REACH

As outlined in the ECHA Guidance on information requirements and chemical safety assessment, Part F: Chemical Safety Report (ECHA 2008a), the main goal of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results, with regard to the standard elements of the CSA. The report should be readily understandable as a stand-alone document. The principles applied, the assumptions made and the conclusions drawn should be transparent. The key data should be easily identifiable without the need to revert to the underlying data sets (i.e., the IUCLID 5 substance data set). Therefore only a part of the information reported in the technical dossier (IUCLID 5) is repeated.

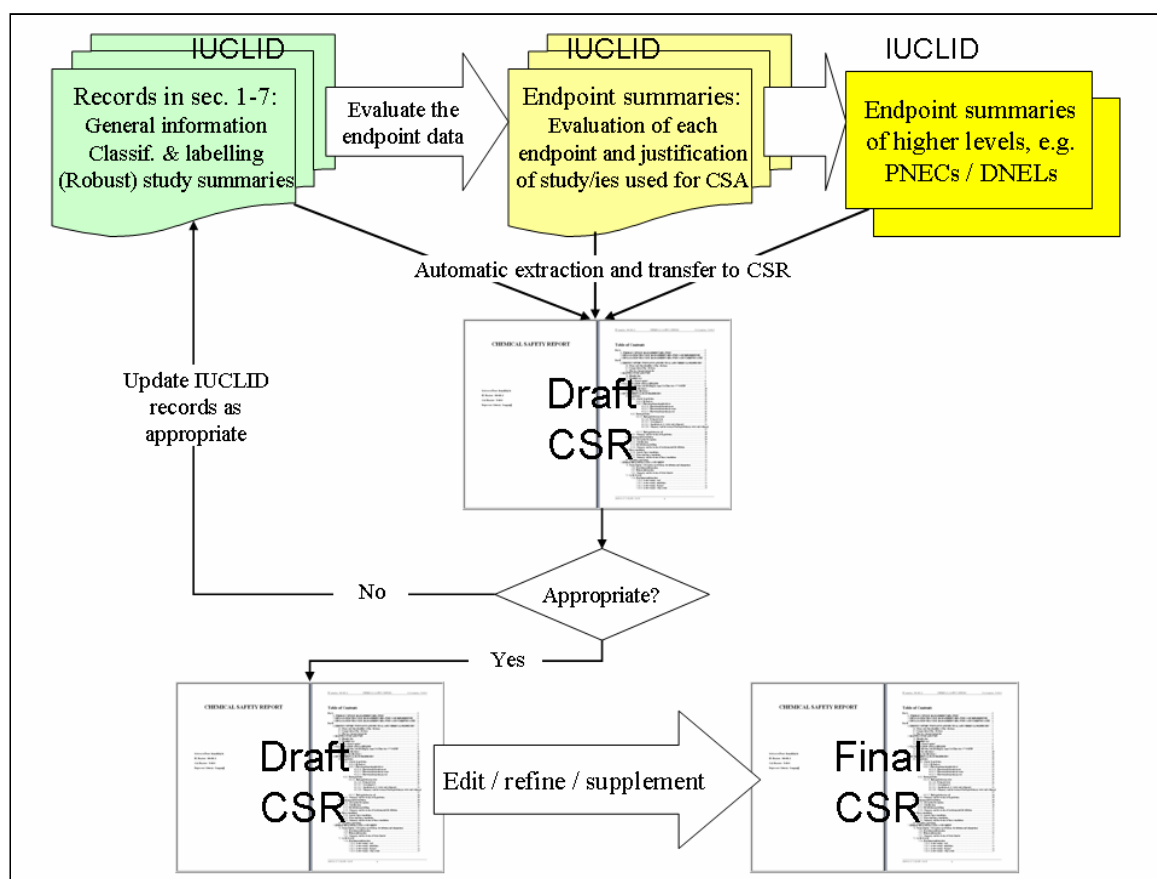
### 1.2. Purpose of the CSR plugin

The CSR plugin has been designed to assist in preparing a CSR. It generates the complete structure of the CSR report including all main and subsections and, in particular, pre-fills the sections for which information can be captured from IUCLID 5, i.e., mainly the CSR sections comprising the hazard assessment.

The plugin generates a CSR document as rtf file (rich text format), which can be edited and further updated as appropriate using any text processing program.

### 1.3. General principles of the CSR preparation using the CSR plugin

The general principles of how the preparation of the CSR is supported by the CSR plugin are shown in the following scheme:



The CSR plugin is thought as an auxiliary which generates a kind of framework of the CSR for use as a starting point. The capture of IUCLID 5 data is controlled by a number of rules used to extract and transfer the most relevant information and filter out less relevant information. However, it should be borne in mind that this goal cannot be reached 100 percent. Manual intervention and update work may be required by the user, particularly in the following cases:

- Relevant information is not captured because it was entered in a field, which is not addressed by the plugin.
- The information captured and transferred to the CSR template is not adequate for a CSR, because
  - it is too comprehensive and/or contains less relevant information, which would expand an overview table inappropriately.
  - it was transferred to the wrong CSR section because relevant structured information is missing, which would serve as target trigger.

As shown in the graphical scheme above, the CSR plugin can be used for the generation of the CSR in an iterative process. That is, entries in the IUCLID 5 source fields can be optimised as appropriate. In this respect, the cyclic improvement of the IUCLID 5 data and re-run of the plugin can be useful in

- verifying that relevant information has been entered in IUCLID 5 and in the appropriate fields;
- minimising any manual adaptations to be done in the CSR.

On the other hand, knowing beforehand what kind of IUCLID 5 information is used or not used by the plugin may prompt the IUCLID 5 user for a more anticipating, i.e., CSR-oriented, completion of the relevant fields (see section [Smart \(CSR-oriented\) data entry in IUCLID](#)).

**Note:**

The CSR plugin is no technical completeness check.

It cannot be guaranteed that all relevant information is captured and/or copied into the appropriate CSR section. The user is responsible to verify that the relevant CSR information is included, and if not, to update the CSR by updating the source records and/or by modifying, supplementing or deleting any information in the CSR manually as appropriate.

Be aware of the risk that any manual changes made to IUCLID 5-borne information in the CSR may result in inconsistencies, if the IUCLID 5 records are not updated accordingly.

## 2. How to install and run the CSR plugin

A separate manual is available which gives guidance on how to install and run the plugin.

**Note:** The CSR plugin can only be used for an IUCLID 5 Substance or Dossier. If it is desired to generate a preliminary CSR based on a Template, e.g. for internal review purposes, the Template has to be assigned to a Substance first, which can then be processed by the plugin.

## 3. Format and general rules underlying the CSR generation

In this section the general rules underlying the CSR generation are explained and exemplified. It is demonstrated how the CSR plugin works and what kind of IUCLID 5 information is generally captured.

**Note:** All IUCLID 5 source fields are specified in PART II: ANNOTATED CSR TEMPLATE

## 3.1. *Layout and format of the CSR generated*

### 3.1.1. Structure

The template for the CSR is structured according to section 7, Annex I of REACH, but provides a more detailed breakdown into subsections as laid down in the template version of July 2008 made available by the ECHA, with some minor changes.

The plugin generates the complete structure of the CSR report including all main and subsections and, in particular, pre-fills the sections for which information can be captured from IUCLID 5, as contained in structured format in (robust) study summaries or in endpoint summaries. That is, mainly the CSR sections comprising the hazard assessment, basic information on manufacture and uses, as well as classification and labeling. Part A of the CSR cannot be handled by the CSR plugin, neither can some parts in section B, i.e., "8. PBT and VPVB assessment", "9. Exposure assessment", and "10. Risk characterisation".

**Note:** It is planned to extend the CSR plugin so that all sections are covered. For this purpose the plugin will be integrated in the Chemical Safety Assessment and Reporting tool (CHESAR).

### 3.1.2. Document file format

The document created is in rich text format (file extension rtf). This format is a document file format used for cross-platform document interchange. Most word processors are able to read and write RTF documents.

**Note:** Font defaults, style presets, table of contents and other functions may vary according to defaults set in your word processing programme if you open rtf documents with other than Microsoft Word/Microsoft Office versions. For instance, you may have to **change the standard font size from 12 to 10 pt in OpenOffice** to avoid distorted documents.

### 3.1.3. Table of contents and list of tables

After the title page of the CSR, a table of contents and list of tables is generated by the plugin, which include the page numbers and hyperlinks that can be used to navigate to the bookmarked destinations.

Predefined styles are applied to headings and table titles (e.g Heading 1; Table Heading) and the Word field code for TOC (Table of Contents) is inserted by the CSR plugin.

When a CSR is generated by the plugin, only the headings "Table of contents" and "List of tables" are printed and the following message: "Please press CTRL+a and afterwards F9 to update the index.". As instructed, the indexes are created if you

- press the key combination CTRL+A (press and hold down the CTRL key and the press the A key on the keyboard) to mark the entire document and then
- press the F9 key on the keyboard.

**Note:** In practice, deleting or adding any headings should normally not occur, because the format of the CSR is a standard format. However, it may be necessary to add or delete tables manually. In such case, it is recommended to copy and paste an existing paragraph with table number and title and update the title as appropriate. The table number and list of tables are updated automatically on marking the relevant paragraph(s) and pressing CTRL+A and then the F9 key.

## 3.2. General rules

In this section the most important rules generally applied by the CSR plugin are described.

### 3.2.1. Transfer of text label (prompts)

In the IUCLID 5 data entry forms, the data entry fields are specified by prompts, which are text labels describing the kind of information expected to be entered (e.g. "Study result type"). In the overview tables generated by the CSR plugin, the following approach is used:

- Text labels are not printed
  - if the kind of information transferred is self-explanatory;
  - if no information is available.
- Text labels are printed if they help understand the meaning of the information or to avoid misinterpretation.
- The data from several source fields can be concatenated and printed after or below one text label.

This is illustrated by the following screenshots:

Method	Results
Eisenia fetida (annelids) short-term toxicity (laboratory study) Substrate: artificial soil OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	LC50 (14 d): soil d.w. (mor NOEC (14 d): d.w. (body w
Folsomia candida (Collembola (soil-	NOEC (4 w)

**Note:** In some cases, prompts are printed even if no IUCLID 5 data are available, thus indicating that either the IUCLID 5 dataset should be updated in this respect or that any information may have to be entered manually. For instance, the prompt "Justification" is always printed if "Data waiving" applies.

### 3.2.2. Discarding picklist phrases "no data", "not applicable" and "other:"

In many IUCLID 5 picklist fields, the phrases "no data" or "not applicable" can be chosen. By convention, these phrases are normally not transferred to the CSR as this would cause confusion or give false meanings. For instance, if no text label is provided, the plain text "no data" would not be understood.

If the phrase "other:" has been selected in a picklist, this phrase is discarded, too. Only the free text entered next to the list field is transferred.

### 3.2.3. Handling information captured from (repeatable) blocks of fields

In IUCLID 5, most results data are included in repeatable blocks of fields, which are grouped in a dialog box and usually displayed in tabular form on the data entry screen. The CSR plugin concatenates all or selected subfields according to specific rules, as illustrated in the following screenshots:

Dissipation half-life of parent compound						
pH	Temp.	Hydrolysis rate constant	Half-life	St. dev.	Type	Remarks
4	25 °C		> 1 yr		(pseudo-)first order (= DT50)	at 0.2 mol /L
7	25 °C		1 – 365 yr		(pseudo-)first order (= DT50)	at 0.2 mol/L
9	25 °C		ca. 30.1 yr		(pseudo-)first order (= DT50)	at 0.2 mol/L



**Table 3. Overview of studies on hydrolysis**

Method	Results	Remarks	Reference
EU Method C.7 (Degradation: Abiotic Degradation: Hydrolysis as a Function of pH)	Half-life (DT50): t1/2 (pH4): > 1 yr at 25 °C; Type: (pseudo-)first order (= DT50) (at 0.2 mol/L) t1/2 (pH7): 1 – 365 yr at 25 °C; Type: (pseudo-)first order (= DT50) (at 0.2 mol/L) t1/2 (pH9): ca. 30.1 yr at 25 °C; Type: (pseudo-)first order (= DT50) (at 0.2 mol/L) Transformation products: not measured	1 (reliable without restriction) key study experimental result	Brekelmans MJC 1999

**Note:** For technical reasons, several pieces of information (e.g. <Remarks>) are set in parentheses, as it would otherwise be difficult to set them apart by punctuation marks.

### 3.2.4. Handling information captured from text fields and rich text areas

In IUCLID 5, several text field types are provided. Information captured from these fields is handled as follows:

- Single-line text field: The content of these fields is transferred without any changes.
- Multi-line text field: The content of these fields is transferred as is. However, multiple line breaks may get lost.
- Rich text (html) area: allows to specify fonts, colours, bullets, and other text attributes and to insert tables. As an improvement to the previous version of the CSR plugin, most of the formatting is kept when processed by the CSR plugin, including tables.

## 4. Guidance on CSR sections B.1 to B.3

The general rules outlined in the preceding section [General rules](#) apply where applicable.

### 4.1. CSR section B.1 Identity of the substance and physical and chemical properties

Specific guidance notes:

- **Table "Overview of physico-chemical properties":**
  - Information is captured from the relevant endpoint summaries rather than from endpoint study records.
  - For guidance on the use of endpoint summary information see section [Information from endpoint summaries](#).
- **Data waiving:** see section [Data waiving information](#).
- **Testing proposal:** see section [Information on testing proposals](#).

### 4.2. CSR section B.2 Manufacture and uses

The tables in the IUCLID 5 section "3.5 Identified uses and exposure scenarios" have been revised in IUCLID version 5.2. The CSR plugin has been updated accordingly.

### 4.3. CSR section B.3. Classification and Labelling

This CSR section is broken down into two subsections.

Specific guidance notes on subsection "3.1 Classification and labelling according to CLP / GHS":

- To distinguish the C&L information transferred from multiple records the heading "Substance: <Name>" is inserted. Make sure that this field is completed appropriately. As a fallback, the heading "Substance: <Reference substance name>" is inserted.

Specific guidance notes on subsection "3.2 Classification and labelling according to DSD / DPD":

- Make sure that the field "Status" in IUCLID 5 section 2.2 is completed with the relevant phrase, i.e., "67/548/EEC annex 1" or "67/548/EEC self classification" or "other:+free text", as this information is used as target trigger. If this field is left blank, any record is transferred to the CSR section "3.2.3 Other classification(s)".
- To distinguish the C&L information transferred from multiple records the heading "Chemical name: <Name>" or, if not available, the heading "Substance: <Reference substance name>" is inserted in CSR sections "3.1 Classification and labelling in Annex I of Directive 67/548/EEC" and "3.2,2 Self classification(s)".
- In CSR section "3.2.3 Other classification(s)", each C&L information starts with the heading "Status: <Status>" if the corresponding IUCLID 5 field is populated with "other:+free text". If this field is blank, the heading "Status: >>>??? IUCLID 5 field empty!<<<" is printed in order to alert the user that this field should be updated.

## 5. Guidance on CSR sections B.4 to B.7 (Hazard assessment)

The general rules outlined in section [General rules](#) apply where applicable.

### 5.1. General approach

The CSR plugin was designed by taking into account the general requirements outlined in the relevant ECHA guidance documents ECHA (2008a), ECHA (2008b) and ECHA (2010) (see [ECHA Guidance documents](#)).

The following approach is applied for generating the hazard assessment sections:

- Overview tables are generated for summarising all relevant and possibly relevant studies as requested in the ECHA guidance documents:
  - Present the key information provided in the IUCLID 5 dataset in a brief table format and reference, rather than repeat the details (cf. ECHA 2008a).
  - In addition to the key studies, information available in other studies could also be used by the registrant as supporting information or as part of a weight of evidence approach (cf. ECHA 2008b).

**Note:** The IUCLID 5 fields "Conclusions" and "Executive summary" are not addressed by the CSR plugin, which is in line with the ECHA guidance that the description of key information should preferably be done in tabular form.

- Data waiving information is captured where REACH foresees this possibility (cf. ECHA 2010).
- Information on testing proposals is captured where the Annexes IX and X of REACH foresee this possibility (cf. ECHA 2008c).
- The conclusions from the hazard assessment should be presented in endpoint summaries of IUCLID 5 which is then transferred to the relevant CSR subsections (cf. ECHA 2008a).

### 5.2. Overview tables for summarising the relevant studies

The following screenshots illustrate (i) the way the overview table has been imported in the CSR plugin and (ii) an example of an overview table generated.

(i) Specification of an overview table

**Table 5.3.1.1 #1: Overview of experimental studies on skin irritation**

Method	Results	Remarks	Reference
in vitro study [REMARK: If field "Type of method" = "in vitro".] <Species> (<Strain>) Coverage: <Type of coverage> (<Preparation of test site>) Vehicle: <Vehicle> <Guideline>[REMARK: If "Qualifier" <> "equivalent or similar to"] equivalent or similar to <Guideline>[REMARK: If "Qualifier" = "equivalent or similar to"] <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) [REMARK: If Overall irritation score is provided.] Primary dermal irritation index (PDII): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) [REMARK: If PDII is provided.] Erythema score: <Score> of max. <Max. score>; <Basis>; <Time point: Time point>; <Reversibility> (<Remarks>) [REMARK: If erythema score is provided.] Edema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) [REMARK: If edema score is provided.] <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) [REMARK: If field "Irritation parameter" is empty or "other:".]	<Reliability> <Purpose flag> <Study result type> <b>Test material</b> [REMARK: See description of rules in introductory part.]	<Author> <Year>

(ii) Example of overview table generated by the CSR plugin

**Table 29: Overview of experimental studies on skin irritation**

Method	Results	Remarks	Reference
rabbit Coverage: occlusive (shaved) Vehicle: sesame oil FDA-Guideline (Federal Register 38, No. 187, 1973, §1500.41)	not irritating Overall irritation score: 0.04 of max. 8.0 (Time point: 24 and 72 hours) Erythema score: 0 (animal: #1-6) (Time point: 24, 48 and 72 hours) Edema score: 1 of max. 3 (animal #2) (24 hours) 0 (animal: #1) (Time point: 3-6, 24 hours) 0 (animal: #1-6) (Time point: 48 and 72 hours)	2 (reliable with restrictions) key study experimental result	Author 1990
in vitro study In Vitro International Corrositex™ assay	not irritating	2 (reliable with restrictions) supporting study experimental result	Author 1990

The following approach is applied for generating overview tables:

- An overview tables is generated if at least one endpoint study record is available in the IUCLID 5 dataset that fulfils the selection criteria specified in the following section [Rules for transferring endpoint study records](#).
- Each overview table is preceded by a default statement such as "The results of experimental studies on skin irritation are summarised in the following table:".

### 5.2.1. Rules for transferring endpoint study records

The general rules apply as outlined in the section [General rules](#), subsections:

Only endpoint study records are captured fulfilling the following selection criteria:

- Criterion #1: Field "Purpose flag" is populated, i.e. the record is flagged as "key study", "supporting study", "weight of evidence" or "disregarded study".
- Criterion #2: Only in some special cases an additional IUCLID field is used to trigger the transfer to a given target section in the CSR. For instance, records in IUCLID sections 7.10.1, 7.10.2, 7.10.3 and 7.10.5 can only be processed if the target section is indicated in the field "Endpoint addressed".

**Note:**

In the first plugin version, the selection criterion "field "Author" is not blank" was used as indication that the record is a study summary. This criterion has been abandoned, because the updated TCC tool (Technical Completeness Check) clearly distinguishes between Data waiving records and records containing study summaries flagged in the field "Purpose flag".

### 5.2.2. Sorting rules

#### 5.2.2.1. Data from multiple endpoint study records

When data from multiple records are inserted in a CSR table, the order is controlled by the following sort rules:

- (I.) Endpoint-specific criteria (if applicable): (1) e.g. freshwater; (2) e.g. saltwater; (3) etc;
- (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study";
- (III.) Additional endpoint-specific rules where appropriate.
- (IV.) If multiple records fulfill the same combination of sorting criteria (e.g. several key studies of type freshwater), the order of records used in the source IUCLID 5 is adhered to.

**Note:** In the tables of "Human information" sections (Table # "Overview of exposure-related observations on ... in humans"), the primary sort rule is determined by the source section for technical reasons. This means that any relevant records from section 7.10.1 are inserted first, followed by those from 7.10.2, etc.

#### 5.2.2.2. Data from multiple fields within the same endpoint study record

Data from multiple fields or blocks of fields are normally ordered as entered in the IUCLID 5 source field(s), unless specific sorting criteria apply. For instance, any NO(A)EL values from repeated dose toxicity studies are sorted first, followed by other effect levels such as LO(A)ELs.

### 5.2.3. Elements included in overview tables

#### 5.2.3.1. Information on method (Guideline, Principles of method, specific fields)

In the column "Method", the key information is inserted, which includes specific descriptors such as Test type, Species, Route of administration, Exposure duration and the following generic descriptors:

- Guideline:
  - No text label (prompt) is printed.
  - Phrases "according to", "no guideline followed", "no guideline available", and "no guideline required" are ignored.
  - "equivalent or similar to <Guideline>" is printed if this phrase has been selected in the field "Qualifier" preceding the field "Guideline".
- Principles of method if other than guideline:
  - No text label (prompt) is printed.
  - Any value from this field is only printed if field "Guideline" is empty.

#### 5.2.3.2. Information on study results

In the column "Results", the most relevant study results and conclusions are inserted. In most cases structured fields are extracted, e.g. "Effect levels" or "Interpretation of results". In some cases multi line free text fields (up to 2000 characters capacity) or text areas are addressed in addition or exclusively. In these cases, manual intervention may be necessary to ensure that the tables contain only brief descriptions of the relevant information. See also section [How to avoid lengthy texts in CSR overview tables](#).

Examples:

- Several CSR sections: Field "Principles of method if other than guideline"
- CSR section "5.1 Toxicokinetics": Fields "Doses / concentrations", "Details on in vitro test system (if applicable)".  
Note: In IUCLID 5.1 also a number of fields in the Results part were designed as multiline free text fields, namely "Absorption", "Distribution in tissues", "Excretion". In IUCLID 5.2, these fields have been included in the block "Main ADME results" and limited to 255 characters each.
- Several CSR sections: The "Results" column of Table "Overview of exposure-related observations on ... in humans" includes information from the following free text fields: "Results", "Results of examinations", "Outcome of incidence"

#### 5.2.3.3. Information on test material identity

In the column "Remarks", the identity of the test material used in the study is inserted under the following conditions:

- Print "**Test material (<Identifier\_sec\_1.1>): <Identity\_sec\_1.1>**" if the "Test material identity" can be identified as being the same as that defined in section 1.1, either as based on the comparison of standard identifiers (EC name, IUPAC name, CAS name, CAS number, or EC number) or if "yes" is indicated in the field "Identity of test material same as for substance defined in section 1 (if not read-across)". The latter condition has no bearing in the case of referenced records (i.e. either records pasted as reference to the source record or records inherited from an "Inherit Template").

As a rule always the same identifier is captured from section 1.1 and printed according to the priority EC name, IUPAC name, CAS name, CAS number, or EC number.

- Print "**Test material (<Identifier>): <Identity>**" (actual test material ID specified in the record) if the "Test material identity" cannot be identified as being the same as that defined in section 1.1. The following cases can occur:
  - The "Test material identity" based on standard identifiers is different from that defined in section 1.1. In this case one standard identifier is printed according to the priority EC name, IUPAC name, CAS name, CAS number, or EC number.
  - No standard identifiers are available, but only non-standard identifier(s). In this case one non-standard identifier is printed according to the priority Common name, TSCA, other:.  
Note: If the only available identifier is "other:", but with no text entered in the associated text field, this is handled as if the field "Identifier" was left blank.
- If read-across is identified add the following additional default text "**(See endpoint summary for justification of read-across)**" after "Test material (<Identifier>): <Identity>".  
Note: This is only triggered by the phrase "read-across ..." in field "Study result type". The approach used previously, i.e. to assume read-across any time the test material identity is different from that in section 1.1 independently of the field "Study result type" has been abandoned, because this would falsely characterize cases as read-across which are not intended so, for instance when a metabolite was used in a study for examining the metabolism scheme.
- In any ambiguous cases (as far as they can be identified), an error message is printed to advice the user that the underlying IUCLID source fields should be updated, i.e.
  - Test material: >>>??? ID is the same as in section 1.1, although "no" is indicated in field "Identity of test material same as for substance defined in section 1 (if not read-across)" [only in case of non-referenced records]
  - Test material: >>>??? ID not the same as in section 1.1, although "yes" is indicated in field "Identity of test material same as for substance defined in section 1 (if not read-across)"<<< [only in case of non-referenced records]
  - Test material: >>>??? ID missing in IUCLID<<<
  - ">>>??? Read-across is indicated in field "Study result type" although test material is same as in section 1.1.<<<"
  - >>>??? Read-across is indicated in field "Study result type", although the test material is not specified.<<<
  - Test material: >>>??? Inconsistent identities: <Identifier>n same, but <Identifier>m not same as in section 1.1<<< [If "no" is indicated in the field "Identity of test material same as for substance defined in section 1 (if not read-across)".]

**Note:**

The approach described above has been based on the following peculiarities of IUCLID 5.2 and the Technical Completeness Check (TCC):

- The fields "Test material equivalent to submission substance identity" (in IUCLID 5.2 renamed to "Identity of test material same as for substance defined in section 1 (if not read-across)") and "Test material identity" are not filled in automatically anymore, when a record is created.

- According to the ECHA Submission Manual #5 (ECHA 2010), it is not required to fill in the field "Test material identity", if the field "Identity of test material same as for substance defined in section 1 (if not read-across)" is populated with "yes", except for referenced records (or records inherited from an Inherit Template). Since the latter cannot be edited in

the target dataset, it cannot be excluded that the value entered in this field in the source dataset (i.e. "yes" or "no") gives a wrong meaning in the target dataset.

#### 5.2.3.4. Administrative information (Reliability, Purpose flag, Study result type)

In the column "Remarks", the following administrative information is given:

- Reliability: The value from the corresponding source field is inserted.
- Purpose flag: The value from the corresponding source field is inserted, i.e., either "key study", "supporting study", "weight of evidence" or "disregarded study".
- Study result type: The value from the corresponding source field is inserted, i.e., either "experimental result", "estimated by calculation", "read-across based on grouping of substances (category approach)", "read-across from supporting substance (structural analogue or surrogate)", "(Q)SAR" or free text (if "other:" is selected). "robust study summary"

##### Note:

In IUCLID 5.2, the new phrase "disregarded study" has been added to the picklist in the field "Purpose flag" allowing to explicitly indicate that a study is not used as key study although showing critical results. In the first version of the CSR plugin, such studies were identified based on the workaround "checkbox 'robust study summary' selected AND field 'Purpose flag' empty". This workaround has been abandoned, because records may also be flagged as 'robust study summary', but not with the intention to flag them as "disregarded study".

The phrase "experimental study planned" in field "Study result type" triggers the transfer of the relevant information to the corresponding part in the CSR section (see section [Information on testing proposals](#)).

#### 5.2.3.5. Data source information (References)

In the column "Reference", the bibliographic reference captured from IUCLID 5 is inserted according to the following rules:

- The values of the fields "Author" + "Year" are printed. In case of missing information either of the following default texts is inserted:
  - >>>Author missing<<<
  - >>>Author + Year missing<<<
- The value of field "Author" is truncated if it exceeds 75 characters. This is to avoid very lengthy citations.
- A lower case letter "a, b, c, etc." is inserted after the year (e.g. Smith H 1999a) if the combination "Author + Year" appears in otherwise differing bibliographic references.
- At the end of the CSR a list of full references is printed, as described in section [List of references](#).

**Note:** The plugin can identify duplicates (i.e., identical contents in all subfields of "Reference") only if identical spelling and format is used. For instance, if the same author or authors have been entered with even slight different spelling or punctuation, they are identified as different citations. Example:

Smith E (1999)

Smith E. (1999) [period after first name initial]

Smith, E. (1999) [comma after last name; period after first name initial]

Even if all other bibliographic data were identical, three citations would be printed in the list of references (see [List of references](#)).

Bibliographic references are often copied from other sources using different formats. It is recommended to update at least those references in IUCLID 5 that could otherwise not be identified easily in the CSR.

### **5.3. Data waiving information**

Data waiving information is captured where REACH foresees this possibility (cf. ECHA 2010). The following rules apply:

- If the field "Data waiving" is populated, the values of this and the field "Justification for data waiving" are captured and inserted under the CSR heading "Data waiving" only if the field "Purpose flag" is empty.
- If, in the same endpoint study record, "Data waiving" is indicated and the administrative fields are populated that characterise the record as study summary, i.e., "Purpose flag", the data waiving information is ignored, while the relevant study summary information is transferred to the overview table.
- If data waivers for several different data requirements are possible, the heading "Information requirement: <Type of study>" is printed and, as far as possible, the type of study is indicated automatically (e.g. "in vitro mammalian cell micronucleus test (chromosome aberration)").

**Note:** This approach reflects the TCC and the Data Submission Manual #5 (ECHA 2010) according to which "an individual Data waiving record should stand alone and not be mixed with other data such as existing study summaries".

## **5.4. Information on testing proposals**

Information on testing proposals is captured where the Annexes IX and X of REACH foresee this possibility (cf. ECHA 2010). The following rules apply:

- If the field "Study result type" contains the phrase "experimental study planned", the values of the following fields are captured and inserted under the CSR heading "Testing proposal":
  - Guideline
  - Study period
  - Principles of method if other than guideline
  - Specific fields characterising the study design, e.g. Study type, Type of method, Test organisms (species).
- If testing proposals for several different data requirements are possible, the heading "Information requirement: <Type of study>" is printed and, as far as possible, the type of study is indicated automatically.

## **5.5. Information from endpoint summaries**

In the hazard assessment part of the CSR, the human health hazard, physicochemical hazard and environmental hazard should be assessed and reported in the endpoint summaries in IUCLID 5.

### **5.5.1. Information captured from IUCLID 5 endpoint summaries**

In the IUCLID 5 Endpoint sections 4 to 10, Endpoint summary records can be created, which can be used to give an appraisal of all data compiled in a given Endpoint section. Hence, an endpoint summary addresses, in a very condensed form, the most relevant and reliable data or provides a weight of evidence evaluation based on several studies.

Endpoint summary records can also be created at a higher level, i.e., for main sections. At the highest level of the main sections "6. Ecotoxicological Information" and "7. Toxicological information", specific summary templates are provided for recording more integrated information, i.e. PNECs and DNELs, respectively, including relevant input parameters.

Each CSR section related to hazard assessment includes a subsection titled "Summary and discussion of ...", to which the information contained in the endpoint summary fields is transferred, as illustrated in the following screenshot example:

Illustration of transfer of endpoint summary information to the CSR

The screenshot shows the CSR tool interface with a callout box highlighting the transfer of information. The callout box, titled "5.7.3. Summary and discussion of mutagenicity", contains the following text:

Substance X was evaluated for its mutagenic and genotoxic potential in vitro and in vivo. Overall the data summarised do not indicate any mutagenic or genotoxic potential of the substance.

**In vitro tests**

Substance X was tested in an Ames test (Smith and Wallace, 1998). Six concentrations (3, 18, 90, 450, 2250 µg/plate) of the test material were applied to 6 different strains of Salmonella typhimurium (TA 1535, TA 100, TA 102, TA 1537, TA 1538 and TA 98) in the absence or presence of S9 -mix. The substance did not induce reverse mutations in the presence or absence of S9-mix in the tested strains.

In a chromosome aberration test (Blacksmith, 1999), substance X did not induce structural chromosomal aberrations in cultured human lymphocytes in concentrations up to 10 mg/mL .....

**In vivo tests**

.....

The following information is taken into account for any hazard / risk assessment:

- In vitro: negative in Ames test with S. typhimurium TA 1535, TA 1537, TA97, TA 98, TA 100, TA102 with and without metabolic activation (EU Method B.13/14)
- In vitro: negative in mammalian chromosome aberration test with human lymphocytes (EU Method B.10)

.....

**Value used for CSA: Genetic toxicity: negative**

**Justification for classification or non classification**

There are conclusive but not sufficient data for the classification of substance X with regard to mutagenicity / genetic toxicity.

The screenshot also shows the "Administrative Data" section with "EU: REACH" selected, the "Short description of key information" section with two entries: "- In vitro: negative in Ames test with S. typhimurium TA 1535 d 8.13/14" and "- In vitro: negative in mammalian chromosome aberration test", the "Key parameter (optional)" section with "Genetic toxicity" set to "negative", and the "Discussion" section with a text area containing the same summary text as the callout box. Arrows indicate the flow of information from the discussion field to the key parameter field and from the discussion field to the callout box.

**Note:** In IUCLID 5 Substance or Template datasets, only one endpoint summary record per section can be created. However, multiple endpoint summary records can occur in a Substance dataset in the following cases:

- (i) If a Template has been assigned to a Substance and in both datasets an endpoint summary record was created for the same IUCLID 5 section.
- (ii) If an IUCLID 4 dataset was migrated to IUCLID 5, multiple records mapped to an endpoint summary appear as multiple endpoint summary records in IUCLID 5.

The CSR plugin captures all endpoint summary records. It is up to the user to update the IUCLID 5 dataset and ensure that any multiple endpoint summary records are cleared.

The following fields are captured from endpoint summaries, if available:

- **Field "Discussion":** The information from this field is inserted in the CSR normally after the heading "Summary and discussion of ...". In section "B.1.3 Physico-chemical properties", it is transferred to the overview table.  
In this IUCLID 5 field, the assessment made for the given endpoint should be described, including the rationale for the choice of the key study(ies). 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 should be justified.
- **Short description of key information:** The information from this field is normally inserted in the CSR after the default statement "The following information is taken into account for any hazard / risk assessment:". In section "B.1.3 Physico-chemical properties", it is transferred to the overview table.  
In this IUCLID 5 field a short description of the most relevant endpoint data should be included,

i.e., the most relevant details, e.g. the test guideline used, test organism and exposure duration, and the key results. Also several key studies can be referenced, particularly if several data requirements are discussed, e.g., in vitro vs. in vivo or gene mutation vs. chromosome aberration in the section "7.6 Genetic toxicity". In general, the characterisation of the endpoint data should be kept as concise as possible and not repeat verbatim the narrative in the field "Discussion". Examples:

- Melting point: 54.6-55.8 °C at 1,013 hPa (OECD 102)
  - Biodegradation in water: screening tests: Not readily biodegradable: 0 - 8% (BOD) in 28 days; 0 - 1% (HPLC) in 28 days (OECD 301C)
  - Genetic toxicity: In vitro gene mutation (Ames test): *S. typhimurium* TA 100, TA 1535: positive with and without metabolic activation (equivalent to OECD 471)
- **Key value for chemical safety assessment:** The information from field(s) subsumed under this heading is inserted in the endpoint-related CSR summary subsections after the default statement "Value used for CSA:". In addition, the key values from the toxicological endpoints are used to generate the table "Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment." in CSR section 5.11.1.

Note: In the IUCLID 5, only a minimum number of structured and hence, searchable fields are provided as "Key value". This has been foreseen for the use of estimation tools. Key values are intended to condense the data summarised in the field "Short description of key information" 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.

- **Justification for classification or non-classification:** The information from this field, if available, is inserted in the CSR after the heading "Justification for classification or non classification".  
The registrant has to determine the classification and labelling of the substance (cf. ECHA 2008b). The rationale for the decision for a classification can be clearly documented in each of the relevant endpoint summary sections. For example the classification for the environment should be justified under the endpoint summary for ecotoxicological information, the classification for physico-chemical properties and human health should be justified under the relevant endpoint summary (e.g. under acute toxicity, flammability, etc.).  
If the information is inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result. He should also indicate for each endpoint for which no classification is proposed whether this is based on conclusive data, inconclusive data or lack of data..

The information from endpoint summaries of the main ecotoxicological and toxicological sections is transferred as follows:

- **IUCLID 5 section "7. Toxicological information" is transferred to the CSR section "B.5.11.2. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects":**
  - The DNEL(s)/DMEL(s) or qualitative statements are transferred to the tables "DN(M)ELs for workers" and "DN(M)ELs for the general population" as well as the field "Justification for (no) DN(M)EL derivation / applied AFs".
  - The information from the "Discussion" fields is inserted after each of these tables.
- **IUCLID 5 section "6. Ecotoxicological Information" is transferred as follows:**
  - The PNEC (water / sediment) values or qualitative statements are transferred to the CSR section "B.7.1.2 Calculation of Predicted No Effect Concentration (PNEC)".

- The PNEC (soil) values or qualitative statements are transferred to the CSR section "B.7.2.2 Calculation of Predicted No Effect Concentration (PNEC soil)".
- The PNEC (STP) values or qualitative statements are transferred to the CSR section "B.7.4.2 PNEC for sewage treatment plant".
- The PNEC (oral) values or qualitative statements are transferred to the CSR section "B.7.5.3 Calculation of PNECoral (secondary poisoning)".
- The information from the field "Environmental classification justification" is inserted in the CSR section "B.7.6 "Conclusion on the environmental hazard assessment and on classification and labelling".

**Note:** The field "Discussion" in the endpoint summary of IUCLID 5 section "6. Ecotoxicological Information" is transferred to the CSR section B.7.6 "Conclusion on the environmental hazard assessment and on classification and labelling".

### 5.5.2. Summary information to be added manually

With this plugin version all relevant CSR elements of section B are automatically completed with IUCLID 5 data except for the following sections:

- Section 8: PBT AND vPvB ASSESSMENT
- Section 9: EXPOSURE ASSESSMENT
- Section 10: RISK CHARACTERISATION

**Note:** It is planned to extend the CSR plugin so that all sections are covered. For this purpose the plugin will be integrated in the Chemical Safety Assessment and Reporting tool (CHESAR).

### ***List of references***

At the end of the CSR a list of full references is printed according to the following rules:

- The references are sorted lexicographically, i.e., alphabetically.
- In the case of ambiguous references, the lower case letter inserted after the year of any citations ("Author + Year") is also inserted in the full reference.
- In the case that either the field "Author" or "Author" and "Year" is/are empty, the default text >>>Author missing<<< or >>>Author + Year missing<<< is inserted.

**Note:**

As set out in section [Data source information \(References\)](#), the plugin can identify doublets (i.e., identical contents in all subfields of "Reference") only if identical spelling and punctuation is used in all subfields of a reference.

As the references are sorted lexicographically, references with the same first author are not necessarily sorted by the year. For instance, the following output would occur:

- Smith A, Cochran S, Adrian V. (2000)....
- Smith A. et al. (1984)....
- Smith A., Wallace W. and Adrian V. (1989)....

## 6. Smart (CSR-oriented) data entry in IUCLID 5

In this section, hints are given on how to reduce any manual update work, after running the CSR plugin, by taking into account what kind of IUCLID 5 information is used or not used by the plugin.

As can be seen from the Annotated CSR template (see PART II: ANNOTATED CSR TEMPLATE), only selected IUCLID 5 fields are addressed by the CSR plugin. With a few exceptions, rather unspecific text fields are not captured, such as fields of the type "Details on ..." or the rich text area "Any other information on materials and methods incl. tables", "Any other information on results incl. tables" or "Overall remarks". Otherwise too much text would compromise the readability of the overview tables.

CSR-oriented data entry in IUCLID 5 is driven by the question of what pieces of information should occur in the CSR table. In the following subsections, some examples are presented which illustrate the before-and-after look of CSR tables depending on the completion of relevant IUCLID 5 fields. Although the examples are taken from selected endpoint sections, the principles of the guidance given can be applied to other sections as well. In brief, the tips given by these examples can be summarised as follows:

- Use an appropriate "Results" field that is captured by the plugin for specifying the purity or composition of the test material, if relevant for the judgement of the study results.
- Avoid empty "Method" cells in CSR overview tables. In the case of non-guideline studies, fill in the field "Principles of method if other than guideline" and, if provided, other fields addressed by the plugin. (Note that this is partly also required by the TCC tool.)
- Avoid empty "Results" cells in CSR overview tables. In the case of results that seem not to fit into structured field(s) enter them in a "Remarks" field or another adequate field.

**Note:** With IUCLID version 5.2 a "Remarks" field is provided in the structured Results part of nearly all endpoint sections. The CSR plugin has been updated accordingly.

The TCC tool (cf. ECHA 2010) allows entering, in "rare cases", explanatory text either in the appropriate "Remarks" field or the field "Any other information on results incl. tables", if the basic fields cannot be completed. To avoid empty cells in the CSR tables, it is highly recommended to enter at least the most relevant information in the "Remarks" field.

- Avoid lengthy texts in CSR overview tables by entering only the most relevant details in CSR-related fields, but including any comprehensive narratives in text areas such as "Any other information on results incl. tables".

**Note:** It may be sensible to describe any peculiarities of a study in the IUCLID 5 endpoint summary instead of directly in the overview table in the CSR. However, the requirement set out by REACH should be adhered to, i.e., the key data should be easily identifiable in the CSR without the need to revert to the underlying data sets (i.e., the IUCLID 5 data set). See [CSR requirements under REACH](#).

### 6.1. How to get information on the test material into the CSR

Data on the purity or composition of the test material are normally entered in the IUCLID 5 field "Details on test material". This field is not captured by the CSR plugin, which is no problem if the test material used in a study is equivalent to the specification given in IUCLID 5 section 1.1. However, in the case that the results data would be ambiguous without indicating the specification of the test material used, it should be specified in an appropriate "Remarks" or other field.

**Note:** The TCC tool (cf. ECHA 2010) allows to specify the test material identity either in the field block "Test material identity" or the field "Details on test material". Since the latter is not captured by the CSR plugin, it is highly recommended to use the field block "Test material identity" for the intended purpose and to enter only additional details in field "Details on test material" such as purity.

**Example: IUCLID 5 section "7.2.1 Acute toxicity: oral"**

The specification of the overview table for the CSR section "5.2.1.1 Acute toxicity: oral" is as follows:

**Table #. Overview of experimental studies on acute toxicity after oral administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

Assuming that a product containing the submission substance as active ingredient was used as test material in the sample study summarised in the screenshot below, the effect level presented would ambiguously indicate whether it is based on the product or the active ingredient included in the product.

**Table 16. Overview of experimental studies on acute toxicity after oral administration**

Method	Results	Remarks	Reference
rat (Wistar) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD50: 998 mg/kg bw (male/female)	2 (reliable with restrictions)  key study  experimental result	Smith E (1999)

This shortcoming can be overcome by specifying the test material in the IUCLID 5 subfield "Remarks" of the repeatable field block "Effect levels". It can even be useful to indicate both effect levels, i.e., the one based on the product and the one based on the active ingredient, as shown in the following screenshots:

The image shows two tables. The top table is titled "Effect levels" and has columns: Sex, Endpoint, Effect level, 95% CL, and Remarks. It contains two rows: one for "male/female" with "LD50" endpoint and "998 mg/kg bw" effect level, and another for "male/female" with "LD50" endpoint and "120 mg/kg bw" effect level. The "Remarks" column for the second row contains "based on product (12% act. ingr.)" and "based on act. ingr.". The bottom table is "Table 16. Overview of experimental studies on acute toxicity after oral administration" with columns: Method, Results, Remarks, and Reference. It has two rows. Arrows point from the "Effect levels" table to the "Results" column of "Table 16": one arrow points from the first row of "Effect levels" to the first row of "Table 16", and another arrow points from the second row of "Effect levels" to the second row of "Table 16".

**Note:** In the toxicological sections of IUCLID 5.2 the repeatable field block "Effect levels" has been extended with the field "Based on", which allows selecting this kind of information from a picklist (e.g. test mat. or act. ingr.). Additional explanations (e.g. 12% act. ingr.) can be entered in the supplementary text field associated with this new field.

**Example: IUCLID 5 section "6.1.3 Short-term toxicity to aquatic invertebrates"**

The specification of the overview table for the CSR section "7.1.1.2.1 Short-term toxicity to aquatic invertebrates" is as follows:

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

In the field block "Effect concentrations" of all environmental toxicity sections of IUCLID 5, the distinct subfield "Conc. based on" is provided for specifying whether the result is based on the "test mat." or "act. ingr.". In addition further details, e.g. the concentration of the active ingredient, can be entered in the supplementary remarks field, if they are important for the judgment of the study results.

The first example in the following screenshot shows an EC50 based on the active ingredient with no further details on the test material. In the second example, the concentration of the active ingredient had been entered in the supplementary remarks field and appears in the CSR table set between parentheses (circled).

Method	Results	Remarks	Reference
<i>Daphnia magna</i> freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 1.8 mg/L act. ingr. (nominal) based on: mobility	1 (reliable without restriction) key study experimental result	Mayr R. (1998)
<i>Daphnia magna</i> freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 1.8 mg/L act. ingr. (12% in product) (nominal) based on: mobility	1 (reliable without restriction) key study experimental result	Mayr R. (1998)

## 6.2. How to get important methodological information into the CSR

### Example: IUCLID 5 section "5.1.1 Phototransformation in air"

The specification of the overview table for the CSR section "4.1.1.2.1. Phototransformation in air" is as follows:

**Table #. Overview of studies on phototransformation in air**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity>	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <%Degr.> after <Sampling time> <Sampling time, unit> (<Test condition>) Quantum yield: <Quantum yield (for direct photolysis)> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

The first screenshot below shows the summary of an estimation study where information is missing in the column "Method". The reason is that all methodological information was obviously entered in fields that are not addressed by the CSR plugin, e.g. "Any other information on materials and methods incl. tables". In addition, the results data presented may also benefit from additional information.

**Table 4. Overview of studies on phototr ansformation in air**

Method	Results	Remarks	Reference
	Half-life (DT50): 47.78 h	2 (reliable with restrictions) key study estimated by calculation	Smith E and Mayr R (2005)

While such a minimal approach may be acceptable for summarising less relevant studies, some more basic information should appear in the CSR for key studies or studies used for weight of evidence evaluation. Filling in the fields "Principles of method if other than guideline" and "Estimation method (if used)" and "Test condition" (in field block "Dissipation half-life") would improve the output, as illustrated by the following screenshots:

Transfer of data from IUCLID sec. "5.1.1 Phototransformation in air" to the CSR overview table

Principles of method if other than guideline  
Determination of the photochemical and oxidative decomposition according to the Atkinson calculation method

Method	Results	Remarks	Reference
Determination of the photochemical and oxidative decomposition according to the Atkinson calculation method  AOPWIN, Atmospheric Oxidation Programme v1.92. Basis: - Calculation of tropospheric half life using the following relation: $t_{1/2} = \ln 2 / k_{OH} \times [OH]$ . - Concentration of OH radicals in the troposphere: $0.5 \times 10^6$ molecule $cm^3$ considering 24 hours irradiation per day.	Half-life (DT50): 47.78 h (calculated tropospheric half life using $k_{OH}$ )	2 (reliable with restrictions)  key study  estimated by calculation	Smith E and Mayr R (2005)

Study design  
Estimation method (if used)

AOPWIN, Atmospheric Oxidation Programme v1.92. Basis:  
 - Calculation of tropospheric half life using the following relation:  $t_{1/2} = \ln 2 / k_{OH} \times [OH]$ .  
 - Concentration of OH radicals in the troposphere:  $0.5 \times 10^6$  molecule  $cm^3$  considering 24 hours irradiation per day.  
 - Overall OH rate constant :  $k_{OH} = 4.0422 \times 10^{-12} \text{ cm}^3 \text{ molecule}^{-1} \text{ sec}^{-1}$ .

Dissipation half-life of parent compound

DT50  h

Test condition:

### 6.3. How to get important information on study results into the CSR

#### Example: IUCLID 5 section "5.1.1 Phototransformation in air"

In the above [Example: IUCLID 5 section "5.1.1 Phototransformation in air"](#), the results data presented may also benefit from additional information.

This can be achieved by entering not only the half-life in field the block "Dissipation half-life", but using the subfield "Test condition" for entering additional information as shown in the last screenshot in section [Example: IUCLID 5 section "5.1.1 Phototransformation in air"](#).

**Example: IUCLID 5 section "5.1.2 Hydrolysis"**

The specification of the overview table for the CSR section "5.1.2 Hydrolysis" is as follows:

**Table #. Overview of studies on hydrolysis**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)>	Half-life (DT50): t1/2 (pH <pH>): <Half-life> at <Temp.>; Rate constant: <Hydrolysis rate constant>; Type: <Type> <(Remarks)> Recovery (in %): pH <pH>: <%Recovery> at <Temp., value> <Temp., unit> after <Duration> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

The first screenshot below shows the summary of a study where information is missing in the column "Results".

**Table 6. Overview of studies on hydrolysis**

Method	Results	Remarks	Reference
OECD Guideline 121 (Estimation of the adsorption coefficient (Koc) on soil and on sewage sludge using HPLC) Draft 1999		2 (reliable with restrictions) key study experimental result	Company (2001)

The reason for the missing information is that the result was entered in the rich text area "Any other information on results incl. tables" in narrative form: "The test substance was not stable under test conditions and hydrolysed completely (100 %) within 8 hours at pH 7 and 20°C."

Although the result "100 % hydrolysis within 8 hours at pH 7 and 20°C" seems not fit into one of the source fields specified in the table above, it can be documented using an appropriate "Remarks" field. As shown in the following screenshot, the field block "Dissipation half-life" was used and the information "100 % hydrolysis after 8 h" was entered in the subfield "Remarks".

Transfer of results data from IUCLID sec. "5.1.2 Hydrolysis" to the CSR overview table

**Repeatable block of fields**  
 Update the fields as instructed by the online Help

pH: 7  
 Temp: 20 °C  
 Hydrolysis rate constant: [ ]  
 Half-life: [ ]  
 St. dev: [ ]  
 Type: [ ]  
 Remarks (e.g. regression equation, r<sup>2</sup>, DT90): 100% hydrolysis after 8 h

**Overview of studies on hydrolysis**

Method	Results	Remarks	Reference
1 (Estimation of the adsorption coefficient (Koc) on soil and on sewage sludge using HPLC) Draft 1999	Half-life (DT50): t1/2 (pH7): at 20 °C (100% hydrolysis after 8 h)	2 (reliable with restrictions) key study experimental result	Company (2001)

Another possibility would be to use the field block "Total recovery of test substance (in %)" and enter "0" in subfield "%Recovery" and the conditions in the relevant subfields "pH", "Temp." and "Duration". It could also be considered to enter a half-life value of "< 8 h" and add the actual result in the "Remarks" field as done above.

**Note:** In most cases, at least one field is available that can be used to enter free text for documenting any results that would not fit into structured field(s). If no "Remarks" field is provided, you may use the "other:" option of an appropriate list field.

## 6.4. How to avoid lengthy texts in CSR overview tables

In some cases, IUCLID 5 fields are captured by the CSR plugin that allow for the entry of comprehensive texts. However, in a CSR table, rather concise texts should be included. This can be achieved by entering only the most relevant details in the CSR-related fields, but including any comprehensive narratives in text areas of the type "Details on ..." or the rich text areas "Any other information on materials and methods incl. tables" and "Any other information on results incl. tables".

### **Example: IUCLID 5 section "7.5.1 Repeated dose toxicity: oral"**

The specification of the overview table for the CSR section "5.6.1.1 Repeated dose toxicity: oral" is as follows:

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline>[REMARK: If Qualifier" <> "equivalent or similar to"] <Qualifier> <Guideline>[REMARK: If Qualifier" = "equivalent or similar to"] <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Basis for effect>) (<Basis for effect level / Remarks>)[REMARK: repeat for each record of the block.]	<Reliability> <Purpose flag> <Study result type> <b>Test material</b> [REMARK: See description of rules in introductory part.]	<Author> <Year>

In the following screenshot example, very lengthy text appears in the "Results" column, because the detailed results were entered in the subfield "Basis for effect level / Remarks" instead of the field "Details on results".

**Table 17. Overview of experimental studies on repeated dose toxicity after oral administration**

Method	Results	Remarks	Reference
rat (Wistar) male/female subchronic (oral: gavage) 10, 30, 100 mg/kg/day (actual ingested) Exposure: 90 days (once a day, 7 days per week) OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	NOAEL: 10 mg/kg bw/day (actual dose received) (male/female) (Significantly higher absolute (25% and 58%) and relative (27% and 62%) liver weight was noted in females at 30 and 100 mg/kg/day, respectively, and in males at 100 mg/kg/day (absolute: 48% and relative: 58%). A biologically significant increase in absolute and relative thyroid weight was also noted in rats dosed with 100 mg/kg/day. The absolute weights were increased by 26 and 48% and the relative weights were increased by 38 and 44% in males and females, respectively, when compared to controls.	1 (reliable without restriction) key study experimental result	Company (2002)

Unless the user prefers to edit any CSR tables manually, the revision work can be reduced by entering only the most important results in those IUCLID 5 text fields that are addressed by the CSR plugin, as shown in the following screenshot:

**Table 17. Overview of experimental studies on repeated dose toxicity after oral administration**

Method	Results	Remarks	Reference
rat (Wistar) male/female subchronic (oral: gavage) 10, 30, 100 mg/kg/day (actual ingested) Exposure: 90 days (once a day, 7 days per week) OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	NOAEL: 10 mg/kg bw/day (actual dose received) (male/female) (based on gross pathology / organ weights: liver enlargement; histopathology: hepatocellular hypertrophy)	1 (reliable without restriction) key study experimental result	Company (2002)

**Example: IUCLID 5 section "7.1.1 Basic toxicokinetics"**

The following screenshots show the specification of the overview table for the CSR section "5.1.1 Non-human information (Toxicokinetics)":

**Table 5.1.1\_#1: Overview of experimental studies on absorption, metabolism, distribution and elimination**

Method	Results	Remarks	Reference
in vitro study <i>[REMARK: If field "Type of method" = "in vitro".]</i> <Species> (<Strain>) <Sex> <Route of administration> <i>[REMARK: If section 7.1.1.]</i> Coverage (dermal absorption study): <Type of coverage> <i>[REMARK: If section 7.1.2]</i> Exposure regime: <Duration and frequency of treatment / exposure> Doses/conc.: <Doses / concentrations> <Guideline> <Principles of method if other than guideline>	Main ADME results: <Type>: <Text> Transfer (<Transfer type>): <Observation> (Test No.: <Test No.>) Toxicokinetic parameters: <Toxicokinetic parameters>> (Test No.: <Test No.>) Metabolites identified: <Metabolites identified> Details on metabolites: <Details on metabolites> Evaluation of results: <Interpretation of results>	<Reliability> <Purpose flag> <Study result type> <b>Test material</b> <i>[REMARK: See description of rules in introductory part.]</i>	<Author> <Year>

CSR-oriented data entry means

- entering the most relevant results in the repeatable field block "Main ADME results" (select either "absorption", "distribution in tissues", "metabolism" and/or "excretion" from the picklist of field "Type") and using the multiline text fields "Details on ..." only for recording any further details that should not necessarily occur in the CSR table. (Note: The block "Main ADME results" has been newly introduced in IUCLID 5.2.)
- entering comprehensive narratives, structured with the relevant subheadings, in the rich text area "Remarks on results including tables".

## 7. ECHA Guidance documents

The following ECHA guidance documents have been cited in this document:

- ECHA (2008a) Guidance on Information Requirements and Chemical Safety Assessment. Part F: Chemical Safety Report. May 2008. European Chemicals Agency, Helsinki.
- ECHA (2008b) Guidance on Registration. May 2008. European Chemicals Agency, Helsinki.
- ECHA (2010) Data Submission Manual No. 5. How to complete a Technical Dossier for Registrations and PPORD Notifications. Version 2.3. 25 March 2010. European Chemicals Agency, Helsinki.

## PART II: ANNOTATED CSR TEMPLATE

This part provides a sample CSR Template, filled with the labels or descriptions of the relevant IUCLID 5 source fields instead of real data. In addition, annotations are included which indicate the IUCLID 5 source sections and explain specific rules where appropriate.

### CONVENTIONS

The following conventions are used in the Annotated CSR Template:

- Placeholders for IUCLID 5 source fields are set between less than / greater than signs, i.e., <placeholder>. Example: <Reference substance name>.
- Annotations are set between brackets and formatted in italics and yellow. Examples:
  - *[IUCLID source: section 5.1.1 Phototransformation in air. Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]*
  - *[IUCLID source: Endpoint summary 5.1.1 Phototransformation in air.]*
  - *[If field "Type of method" = "in vitro".]*
- Rules described in Part I of this User's Guide, section [Format and general rules underlying the CSR generation](#), are normally not repeated. Please refer to that section.

# CHEMICAL SAFETY REPORT

**Substance Name:** <Reference substance name>

**Substance Name:** <Chemical name> *[If no <Reference substance name> available.]*

**EC Number:** <Chemical name>

**CAS Number:** <CAS number (EC inventory)>

**CAS Number:** <CAS number (CAS information)> *[Only if no CAS number (EC inventory) available.]*

**Registrant's Identity:** <Legal entity name>

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# **Part A**

## **1. SUMMARY OF RISK MANAGEMENT MEASURES**

## **2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED**

## **3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED**

## Part B

### 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

#### 1.1. Name and other identifiers of the substance

*[IUCLID source: section 1.1 Identification, unless otherwise stated]*

*[Depending on the values of IUCLID fields "Composition" and "Origin" one of the following statements is automatically inserted.]*

The substance <Reference substance name/Chemical name> is an element having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details). *[If field "Origin" = "element"]*

The substance <Reference substance name/Chemical name> is a <Composition> (<Origin>) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details). *[If field "Composition" <> "other:" or <> empty and field "Origin" <> "element".]*

Type of substance <Reference substance name/Chemical name>: <Composition> (composition)[; <Origin> (origin)]. The characteristics and physical–chemical properties are described below (see the IUCLID dataset for further details). *[If field "Composition" = "other:" or empty and field "Origin" <> "element".]*

The following public name is used: <Public name> *[New field in IUCLID 5.2]*

**Table 1. Substance identity**

<b>EC number:</b>	<EC number>
<b>EC name:</b>	<EC name>
<b>CAS number (EC inventory):</b>	<CAS number (EC inventory)>
<b>CAS number:</b>	<CAS number> <i>[If different from &lt;CAS number (EC inventory)&gt;]</i>
<b>CAS name:</b>	<CAS name>
<b>IUPAC name:</b>	<IUPAC name>
<b>Description:</b>	<Description> <i>[Only if none of the standard identifiers are available]</i>
<b>Synonyms:</b>	<Synonyms> <i>[Only if none of the standard identifiers are available]</i>
<b>Annex I index number:</b>	<Index number> <i>[Source: 2.2 DSD - DPD: General information]</i>
<b>Molecular formula:</b>	<Molecular formula>
<b>Molecular weight range:</b>	<RANGE: Molecular weight range>

#### Structural formula:

*[Any image included in the field "Structural formula" is captured and transferred into the CSR template.]*

#### Remarks:

<Remarks>

## 1.2. Composition of the substance

[IUCLID source: section 1.2 Composition]

Name: <Name>

Description: <Brief description>

Degree of purity: <Degree of purity>

**Table 2. Constituents**

Constituent	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	<Remarks>

**Table 3. Impurities**

Impurity	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	<b>Impurity is relevant for C&amp;L of the substance</b> [Insert if this checkbox is selected.] <Remarks>

**Table 4. Additives**

Additive	Function	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Function>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	<b>Additive is relevant for C&amp;L of the substance</b> [Insert if this checkbox is selected.] <Remarks>

## 1.3. Physico-chemical properties

[IUCLID source: endpoint summary record of section 4.1 Appearance/physical state/colour<sup>1</sup> / 4.2 Melting point/freezing point / 4.3 Boiling point / 4.4 Density / 4.6 Vapour pressure / 4.10 Surface tension / 4.8 Water solubility / 4.7 Partition coefficient / 4.11 Flash point / 4.13 Flammability / 4.14 Explosiveness / 4.12 Auto flammability / 4.15 Oxidising properties / 4.5 Particle size distribution (Granulometry) / 4.17 Stability in

<sup>1</sup> As an exception, the endpoint study record(s) are captured from IUCLID section 4.1 (either only those flagged as "key study" or all if no key study indicated) if no endpoint summary value is available. This alternative has been implemented because no endpoint summary was provided for section 4.1 in IUCLID v. 5.1. However, it should be noted that the latter is required as input parameter for the CSA tool Chesar.

organic solvents ... / 4.21 Dissociation constant / 4.22 Viscosity / 4.18 Storage stability and reactivity ... / 4.19 Stability: thermal, sunlight, metals]

**Table 5. Overview of physico-chemical properties**

Property	Results	Value used for CSA / Discussion
Physical state at 20°C and 1013 hPa	<Short description of key information>  [Alternative source: endpoint study record(s), if no endpoint summary value is available for "Physical state ": <Physical state at 20°C and 1013 hPa> <Form> / Colour: <Colour> / <Odour> (source: endpoint study record(s)]	<b>Value used for CSA:</b> <Key value for CSA> <Discussion>
Melting / freezing point	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at 1013 hPa <Discussion>
Boiling point	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at 1013 hPa <Discussion>
Relative density	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> at 20°C <Discussion>
Vapour pressure	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at <Temp.> <Unit> <Discussion>
Surface tension	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> mN/m at 20°C and <Conc.> mg/L <Discussion>
Water solubility	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at <Temp.> <Unit> <Discussion>
Partition coefficient n-octanol/water (log value)	<Short description of key information>	<b>Value used for CSA:</b> Log Kow (Pow): <Key value for CSA> <Unit> at <Temp.> <Unit> <Discussion>
Flash point	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at 1013 hPa <Discussion>
Flammability	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Discussion>
Explosive properties	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Discussion>
Self-ignition temperature	<Short description of key information>	<b>Value used for CSA:</b> <Key value for CSA> <Unit> at 1013

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

		hPa <Discussion>
Oxidising properties	<Short description of key information>	<b>Value used for CSA:</b> Oxidising: <Key value for CSA> <Discussion>
Granulometry	<Short description of key information>	<Discussion>
Stability in organic solvents and identity of relevant degradation products	<Short description of key information>	<Discussion>
Dissociation constant	<Short description of key information>	<b>Value used for CSA:</b> pKa at 20°C: <Key value for CSA> <Discussion>
Viscosity	<Short description of key information>	<b>Value used for CSA:</b> Viscosity at 20°C: <Key value for CSA> <Unit> <Discussion>
Reactivity towards container material	<Short description of key information>	<Discussion>
Thermal stability	<Short description of key information>	<Discussion>

#### **Data waiving**

*[IUCLID source: endpoint study records of sections 4.2 Melting point/freezing point / 4.3 Boiling point / 4.4 Density / 4.6 Vapour pressure / 4.10 Surface tension / 4.8 Water solubility / 4.7 Partition coefficient / 4.11 Flash point / 4.13 Flammability / 4.14 Explosiveness / 4.12 Auto flammability / 4.15 Oxidising properties / 4.5 Particle size distribution (Granulometry) / 4.17 Stability in organic solvents ... / 4.21 Dissociation constant / 4.22 Viscosity / 4.18 Storage stability and reactivity ... / 4.19 Stability: thermal, sunlight, metals]*

**Information requirement:** Melting / freezing point<Data waiving>

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Boiling point

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Relative density

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Vapour pressure

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Surface tension

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Water solubility

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Partition coefficient n-octanol/water (log value)

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Flash point

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Flammability

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Explosive properties

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Self-ignition temperature

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Oxidising properties

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Granulometry

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Stability in organic solvents and identity of relevant degradation products

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Dissociation constant

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Viscosity

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Reactivity towards container material

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Information requirement:** Thermal stability

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### Testing proposal

[IUCSID source: endpoint study records of sections 4.17 Stability in organic solvents ... / 4.21 Dissociation constant / 4.22 Viscosity]

**Information requirement:** Stability in organic solvents and identity of relevant degradation products

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

**Information requirement:** Dissociation constant

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

**Information requirement:** Viscosity

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

### Discussion of physico-chemical properties

<Discussion> [IUCSID source: Endpoint summary: 4. Physical and chemical properties]

## 2. MANUFACTURE AND USES

### Quantities

Table 6. Overview of quantities (in tonnes/year) [IUCSID source: section 3.2 Estimated quantities]

Year	Total tonnage	Own use	Used for article	Used as intermediate under strictly controlled conditions	Used for research purposes
<Year>	Manufactured: <Manufactured> Imported: <Imported>	<Total tonnage for own use>	Imported in article: <Tonnage imported in article> Used in production of article: <Tonnage used in the production of articles>	Transported: <Tonnage used as intermediate Under strictly controlled Conditions (transported)> On-site: <Tonnage used as intermediate Under strictly controlled Conditions (on-site)>	<Tonnage used for research purposes>

<Remarks>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

## 2.1. Manufacture

### Manufacturing process

<Methods of manufacture> **[IUCOLID source: section 3.1 Technological process]**

## 2.2. Identified uses

**[IUCOLID source: section 3.5 Identified uses. Note: In the real CSR documents, the table is formatted in landscape and larger font size.]**

Justification why no identified uses are reported: <Justification why no identified uses are reported>

All identified uses take place in closed system. **[If the corresponding checkbox in IUCOLID section is selected.]**

**Table 7. Uses by workers in industrial settings**

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	as such (substance itself) <i>[If resp. checkbox is selected.]</i> in a mixture <i>[If resp. checkbox is selected.]</i>	<b>Process category (PROC):</b> <Process category> <b>Market sector by type of chemical product:</b> <Market sector by type of chemical product> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Sector of end use (SU):</b> <Sector of end use> <b>Subsequent service life relevant for that use?:</b> <Subsequent service life relevant for that use?> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life>

**Table 8. Uses by professional workers**

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	as such (substance itself) <i>[If resp. checkbox is selected.]</i> in a mixture <i>[If resp. checkbox is selected.]</i>	<b>Process category (PROC):</b> <Process category> <b>Market sector by type of chemical product:</b> <Market sector by type of chemical product> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Sector of end use (SU):</b> <Sector of end use> <b>Subsequent service life relevant for that use?:</b> <Subsequent service life relevant for that use?> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life>

**Table 9. Uses by consumers**

Confidential	IU number	Identified Use (IU) name	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	<b>Chemical product category (PC):</b> <Chemical product category> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Subsequent service life relevant for that use?:</b> <Subsequent service life relevant for that use?> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life>

### **Most common technical function of substance (what it does):**

<Technical functions>

Remarks:

<Remarks>

## 2.3. Uses advised against

[IUCLID source: section 3.6 Uses advised against. Note: In the real CSR documents, the table is formatted in landscape and larger font size.]

**Table 10. Uses by workers in industrial settings advised against**

Confidential	IU number	Use advised against name	Substance supplied to that use	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	as such (substance itself) [REMARK : If resp. checkbox is selected.] in a mixture [REMARK : If resp. checkbox is selected.]	<b>Process category (PROC):</b> <Process category> <b>Market sector by type of chemical product:</b> <Market sector by type of chemical product> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Sector of end use (SU):</b> <Sector of end use> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life> <b>Remarks:</b> <Remarks>

**Table 11. Uses by professional workers advised against**

Confidential	IU number	Use advised against name	Substance supplied to that use	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	as such (substance itself) [REMARK : If resp. checkbox is selected.] in a mixture [REMARK : If resp. checkbox is selected.]	<b>Process category (PROC):</b> <Process category> <b>Market sector by type of chemical product:</b> <Market sector by type of chemical product> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Sector of end use (SU):</b> <Sector of end use> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life> <b>Remarks:</b> <Remarks>

**Table 12. Uses by consumers advised against**

Confidential	IU number	Use advised against name	Use descriptors
<Confidentiality>	<IU number>	<Identified use name>	<b>Chemical product category (PC):</b> <Chemical product category> <b>Environmental release category (ERC):</b> <Environmental release category> <b>Article category related to subsequent service life (AC):</b> <Article category related to subsequent service life> <b>Remarks:</b> <Remarks>

## 3. CLASSIFICATION AND LABELLING

### 3.1. Classification and labelling according to CLP / GHS

[IUCPID source: section 2.1 GHS]

**Substance:** <Name> [Alternatively: Substance: <Reference substance name>, if <Name> is blank.]

**Implementation:** <Implementation>

#### Classification

The substance is not classified [If the checkbox "not classified" is selected.]

The substance is classified as follows: [If either of the "Classification" fields is populated.]

- for physical-chemical properties:

Explosives	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Flammable gases	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Flammable aerosols	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Oxidising gases	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Gases under pressure	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Flammable liquids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Flammable solids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Self-reacting substances and mixtures	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Pyrophoric liquids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Pyrophoric solids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Self-heating substances and mixtures	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Substances and mixtures which in contact with water emits flammable gases	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Oxidising liquids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Oxidising solids	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Organic peroxides	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Corrosive to metals	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>

- for health effects:

Acute toxicity - oral:	<category> (Hazard statement: <hazardStatement> Reason for no classification: <reasonForNoClassification>
Acute toxicity -	<category> (Hazard statement: <hazardStatement>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

dermal: Reason for no classification: <reasonForNoClassification>  
<category> (Hazard statement: <hazardStatement>)  
Acute toxicity - Reason for no classification: <reasonForNoClassification>  
inhalation:  
Skin <category> (Hazard statement: <hazardStatement>)  
corrosion/irritation: Reason for no classification: <reasonForNoClassification>  
Serious damage/eye <category> (Hazard statement: <hazardStatement>)  
irritation: Reason for no classification: <reasonForNoClassification>  
Respiration <category> (Hazard statement: <hazardStatement>)  
sensitization: Reason for no classification: <reasonForNoClassification>  
Skin sensitation: <category> (Hazard statement: <hazardStatement>)  
Reason for no classification: <reasonForNoClassification>  
Aspiration hazard: <category> (Hazard statement: <hazardStatement>)  
Reason for no classification: <reasonForNoClassification>  
Reproductive <category> (Hazard statement: <hazardStatement>)  
Toxicity: Specific effect: <Specific effect>  
Route of exposure: <Route of exposure>  
Reason for no classification: <reasonForNoClassification>  
Reproductive <category> (Hazard statement: <hazardStatement>)  
Toxicity: Effects on Reason for no classification: <reasonForNoClassification>  
or via lactation:  
Germ cell <category> (Hazard statement: <hazardStatement>)  
mutagenicity: Route of exposure: <Route of exposure>  
Reason for no classification: <reasonForNoClassification>  
Carcinogenicity: <category> (Hazard statement: <hazardStatement>)  
Route of exposure: <Route of exposure>  
Reason for no classification: <reasonForNoClassification>  
Specific target organ <category> (Hazard statement: <hazardStatement>)  
toxicity - single: Affected organs: <Affected organs>  
Route of exposure: <Route of exposure>  
Reason for no classification: <reasonForNoClassification>  
Specific target organ <category> (Hazard statement: <hazardStatement>)  
toxicity - repeated: Affected organs: <Affected organs>  
Route of exposure: <Route of exposure>  
Reason for no classification: <reasonForNoClassification>

Specific concentration limits:

Concentration (%)	Classification
<Concentration range>	<Hazard categories>

- for environmental hazards:

Hazards to the <category> (Hazard statement: <hazardStatement>)  
aquatic environment: Reason for no classification: <reasonForNoClassification>  
Hazardous to the <category> (Hazard statement: <hazardStatement>)  
atmospheric Reason for no classification: <reasonForNoClassification>  
environment:  
M-Factor: <M-Factor>

- for additional hazard classes:

Additional hazard <Additional hazard classes>  
classes:  
Additional hazard <Additional hazard statements>  
statements:

**Labelling**

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

---

Signal word: <Signal word>

Hazard pictogram:

<Hazard pictogram>

Hazard statements:

<Hazard statement> (<Additional text>)

Precautionary statements:

<Precautionary statement> (<Additional text>)

Additional labelling requirements (CLP supplemental hazard statement):

<CLP supplemental hazard statement> (Additional text: <Additional text>)

<Additional labelling>

Notes:

<Notes>

## 3.2. Classification and labelling according to DSD / DPD

### 3.2.1 Classification and labelling in Annex I of Directive 67/548/EEC

*[IUCLID source: section 2.2 DSD - DPD; condition: if field "Status" = "67/548/EEC annex I".]*

**Chemical name:** <Name> *[Alternatively: Substance: <Reference substance name>, if <Name> is blank.]*

**Related composition:** <Related composition>

#### Classification

The substance is not classified *[If the checkbox "not classified" is selected.]*

The substance is classified as follows: *[If either of the "Classification" fields is populated.]*

- for physical-chemical properties:

<Explosiveness>  
<Oxidising properties>  
<Flammability>  
<Thermal stability>

- for health effects:

<Acute toxicity>  
<Acute toxicity - irreversible damage after single exposure>  
<Repeated dose toxicity>  
<Irritation / Corrosion>  
<Sensitisation>  
<Carcinogenicity>  
<Mutagenicity - Genetic Toxicity>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Toxicity to reproduction - fertility>

<Toxicity to reproduction - development>

<Toxicity to reproduction - breastfed babies>

- for the environment:

<Environment>

## Labelling

Indication of danger:

<Indication of danger>

R-phrases:

<Risk phrases>

S-phrases:

<Code> (<Additional text>)

Specific concentration limits:

Concentration (%)	Classification
<Concentration range>	<Indication of danger (symbols)>.

Notes:

<Notes>

### 3.2.2 Self classification(s)

[IUCSID source: section 2.2 DSD - DPD; condition: if field "Status" = "67/548/EEC self classification".]

**Chemical name:** <Name> [Alternatively: Substance: <Reference substance name>, if <Name> is blank.]

**Related composition:** <Related composition>

Remarks: <Remarks>

**Table 13. Classification according to Directive 67/548/EEC criteria**

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness	<Explosiveness>	<Reason for no classification>	6.1
Oxidising properties	<Oxidising properties>	<Reason for no	6.3

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

		classification>	
Flammability	<Flammability>	<Reason for no classification>	6.2
Thermal stability	<Thermal stability>	<Reason for no classification>	
Acute toxicity	<Acute toxicity>	<Reason for no classification>	5.2
Acute toxicity- irreversible damage after single exposure	<Acute toxicity - irreversible damage after single exposure>	<Reason for no classification>	5.2
Repeated dose toxicity	<Repeated dose toxicity>	<Reason for no classification>	5.6
Irritation / Corrosion	<Irritation / Corrosion>	<Reason for no classification>	5.3.4 and 5.4.3
Sensitisation	<Sensitisation>	<Reason for no classification>	5.5.3
Carcinogenicity	<Carcinogenicity>	<Reason for no classification>	5.8.3
Mutagenicity - Genetic Toxicity	<Mutagenicity - Genetic Toxicity>	<Reason for no classification>	5.7.3
Toxicity to reproduction-fertility	<Toxicity to reproduction - fertility>	<Reason for no classification>	5.9.3
Toxicity to reproduction-development	<Toxicity to reproduction - development>	<Reason for no classification>	5.9.3
Toxicity to reproduction - breastfed babies	<Toxicity to reproduction - breastfed babies>	<Reason for no classification>	5.9.3
Environment	<Environment>	<Reason for no classification>	7.6

## Labelling

### Indication of danger:

<Indication of danger>

### R-phrases:

<Risk phrases>

### S-phrases:

<Code> (<Additional text>)

### Specific concentration limits:

Concentration (%)	Classification
<Concentration range>	<Indication of danger (symbols)>

### Notes:

<Notes>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

### 3.2.3. Other classification(s)

[IUCALID source: section 2.2 DSD - DPD; condition: if field "Status" = "other:" (free text) or blank.]

Status: <Status> [Alternatively: Status: >>>?? IUCALID field empty!<<<, if <Status> is blank.]

Chemical name: <Name> [Alternatively: Substance: <Reference substance name>, if <Name> is blank.]

Related composition: <Related composition>

Remarks: <Remarks>

Table 9: <Status>

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness	<Explosiveness>	<Reason for no classification>	6.1
Oxidising properties	<Oxidising properties>	<Reason for no classification>	6.3
Flammability	<Flammability>	<Reason for no classification>	6.2
Thermal stability	<Thermal stability>	<Reason for no classification>	
Acute toxicity	<Acute toxicity>	<Reason for no classification>	5.2
Acute toxicity- irreversible damage after single exposure	<Acute toxicity - irreversible damage after single exposure>	<Reason for no classification>	5.2
Repeated dose toxicity	<Repeated dose toxicity>	<Reason for no classification>	5.6
Irritation / Corrosion	<Irritation / Corrosion>	<Reason for no classification>	5.3.4 and 5.4.3
Sensitisation	<Sensitisation>	<Reason for no classification>	5.5.3
Carcinogenicity	<Carcinogenicity>	<Reason for no classification>	5.8.3
Mutagenicity - Genetic Toxicity	<Mutagenicity - Genetic Toxicity>	<Reason for no classification>	5.7.3
Toxicity to reproduction-fertility	<Toxicity to reproduction - fertility>	<Reason for no classification>	5.9.3
Toxicity to reproduction-development	<Toxicity to reproduction - development>	<Reason for no classification>	5.9.3
Toxicity to reproduction - breastfed babies	<Toxicity to reproduction - breastfed babies>	<Reason for no classification>	5.9.3
Environment	<Environment>	<Reason for no classification>	7.6

### Labelling

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

---

Indication of danger:

<Indication of danger>

R-phrases:

<Risk phrases>

S-phrases:

<Code> (<Additional text>)

Specific concentration limits:

<b>Concentration (%)</b>	<b>Classification</b>
<Concentration range>	<Indication of danger (symbols)>

Notes:

<Notes>

## 4. ENVIRONMENTAL FATE PROPERTIES

### General discussion of environmental fate and pathways

<Discussion> [IUCLID source: Endpoint summary 5. Environmental fate and pathways]

### 4.1. Degradation

#### 4.1.1. Abiotic degradation

##### 4.1.1.1. Hydrolysis

[IUCLID source: section 5.1.2 Hydrolysis.]

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The studies on hydrolysis are summarised in the following table:

**Table 14. Overview of studies on hydrolysis**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)>	Half-life (DT50): t1/2 (pH <pH>): <Half-life> at <Temp.>; Rate constant: <Hydrolysis rate constant>; Type: <Type> <(Remarks)> Recovery (in %): pH <pH>: <%Recovery> at <Temp., value> <Temp., unit> after <Duration> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** [IUCLID source: Endpoint summary 5.1.2 Hydrolysis.]

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

### **Value used for CSA:**

Hydrolysis rate constant: <Key value for CSA> at <Temperature> <Unit>

#### 4.1.1.2. Phototransformation/photolysis

##### 4.1.1.2.1. Phototransformation in air

[IUCLID source: section 5.1.1 Phototransformation in air.  
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The studies on phototransformation in air are summarised in the following table:

**Table 15. Overview of studies on phototransformation in air**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity>	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <% Degr.> after <Sampling time> (<Test condition>) Degradation rate constant: <Rate constant> for reaction with <Reaction with>[Repeat for each record of the block.] Quantum yield: <Quantum yield (for direct photolysis)> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### Testing proposal

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

**Discussion** [IUCLID source: Endpoint summary 5.1.1 Phototransformation in air.]

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

**Value used for CSA:**

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Half-life in air: <Key value for CSA> <Unit>

Degradation rate constant with OH radicals: <Rate constant> <Unit>

#### 4.1.1.2.2. Phototransformation in water

[IUCLID source: section 5.1.3 Phototransformation in water.  
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The studies on phototransformation in water are summarised in the following table:

**Table 16. Overview of studies on phototransformation in water**

Method	Results	Remarks	Reference
Study type: <Study type> <Guideline> <Principles of method if other than guideline> <Computational methods> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity> Sensitiser: <Type of sensitiser> (<RANGE_UNIT: Concentration of sensitiser>)	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <% Degr.> after <Sampling time> (<Test condition>) Quantum yield: <Quantum yield (for direct photolysis)> Rate constant: <Rate constant> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### Testing proposal

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Study type:** <Study type>

**Details on method intended:**

<Principles of method if other than guideline>

**Discussion** [IUCLID source: Endpoint summary 5.1.3 Phototransformation in water. ]

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Value used for CSA:**

Half-life in water: <Key value for CSA> <Unit>

**4.1.1.2.3. Phototransformation in soil**

*[IUCLID source: section 5.1.4 Phototransformation in soil.*

*Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]*

The studies on phototransformation in soil are summarised in the following table:

**Table 17. Overview of studies on phototransformation in soil**

Method	Results	Remarks	Reference
Study type: <Study type> <Guideline> <Principles of method if other than guideline> <Computational methods> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity> Details on soil: <Details on soil>	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <% Degr.> after <Sampling time> (<Test condition>) Quantum yield: <Quantum yield (for direct photolysis)> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

**Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Testing proposal**

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Study type:** <Study type>

**Details on method intended:**

<Principles of method if other than guideline>

**Discussion** [IUCLID source: Endpoint summary 5.1.4 Phototransformation in soil.]

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

**Value used for CSA:**

Half-life in soil: <Key value for CSA> <Unit>

## 4.1.2. Biodegradation

### 4.1.2.1. Biodegradation in water

#### 4.1.2.1.1. Estimated data

The estimated data for biodegradation in water are summarised in the following table:

**Table 18. Overview of estimated data for biodegradation in water**

Estimation method	Results	Remarks	Reference
<i>[IUCLID source: section 5.2.1 Biodegradation in water: screening tests. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
<Study result type> <Principles of method if other than guideline> Study design: <Details on study design>	<Interpretation of results> % Degradation of test substance:  <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>)	<Reliability> <Purpose flag>	<Author> <Year>
<i>[IUCLID source: section 5.2.2 Biodegradation in water and sediment: simulation tests. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
<Study result type> <Principles of method if other than guideline> Study design: <Details on study design>	% Degradation of test substance:  <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>)  Half-life:  <Half-life> in <Compartment> (<Remarks>)	<Reliability> <Purpose flag>	<Author> <Year>

#### 4.1.2.1.2. Screening tests

*[IUCLID source: section 5.2.1 Biodegradation in water: screening tests. Sort rule in table: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study". (II.) Field "Oxygen conditions" = (1) "anaerobic"; (2) anaerobic".]*

The test results are summarised in the following table:

**Table 19. Overview of screening tests for biodegradation in water**

Method	Results	Remarks	Reference
Test type: <Test type> <Inoculum or test system> (<Oxygen conditions>) <i>[If "Oxygen</i>	<Interpretation of results> % Degradation of test substance:	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

EC number: <Chemical name> CAS number:  
 <EC number> <CAS number>

<i>conditions = anaerobic" and "Inoculum" &lt;&gt; "anaerobic ...".]</i> <Guideline> <Principles of method if other than guideline>	<% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>)	<b>Test material identity</b> [See description of rules in introductory part.]	
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### Data waiving

**Information requirement:** <Test type>

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### 4.1.2.1.3. Simulation tests (water and sediments)

*[IUCLID source: section 5.2.2 Biodegradation in water and sediment: simulation tests. Sort rule in table: (I) Field "Inoculum or test system" = (1) "natural water"; (2) natural water / sediment"; (3) "natural sediment". (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]*

The test results are summarised in the following table:

**Table 20. Overview of simulation tests for biodegradation in water and sediment**

Method	Results	Remarks	Reference
Test system: <Inoculum or test system> (<Oxygen conditions>) <Guideline> <Principles of method if other than guideline>	Half-life (DT50): <Half-life> in <Compartment> % Degradation of test substance: <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>) Metabolites: <Metabolites>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### 4.1.2.1.4. Summary and discussion of biodegradation in water and sediment

**Discussion (screening testing)** *[IUCLID source: Endpoint summary 5.2.1 Biodegradation in water: screening tests.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Value used for CSA:** Biodegradation in water: <Key value for CSA>

**Discussion (simulation testing)** [IUCLID source: Endpoint summary 5.2.2 Biodegradation in water and sediment: simulation tests.]

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

**Value used for CSA:**

Half-life in water: <Key value for CSA> <Unit> at <Temperature> <Unit>

Half-life in sediment: <Key value for CSA> <Unit> at <Temperature> <Unit>

**Testing proposal** [IUCLID source: section 5.2.2 Biodegradation in water and sediment: simulation tests.]

**Information requirement:** .... ["Simulation testing on ultimate degradation in surface water" is inserted if field "Inoculum or test system" <> "natural sediment". "Sediment simulation testing" is inserted if field "Inoculum or test system" = "natural sediment".]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Test system: <Inoculum or test system> (<Oxygen conditions>)

Source and properties of surface water: <Details on source and properties of surface water>

Source and properties of sediment: <Details on source and properties of sediment>

Study design: <Details on study design>

#### 4.1.2.2. Biodegradation in soil

[IUCLID source: Endpoint summary 5.2.3 Biodegradation in soil.  
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The test results are summarised in the following table:

**Table 21. Overview of simulation tests for biodegradation in soil**

Method	Results	Remarks	Reference
Test type: <Test type> Soil type: <Soil type> (<Soil No.>) <Guideline> <Principles of method if other than guideline>	Half-life (DT50): <Half-life> (<Soil No.>) (<Remarks>) % Degradation of test substance: <% Degradation of test substance> after <Sampling	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

	time> (<Parameter>) (<Soil No.> Evaporation of parent compound: <Determination of evaporation of parent compound> Volatile metabolites: <Determination of volatile metabolites> Residues: <Determination of residues> Metabolites: <Metabolites>		
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### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **Discussion** *[IUCLID source: Endpoint summary 5.2.3 Endpoint summary Biodegradation in soil.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

### **Value used for CSA:**

Half-life in soil: <Key value for CSA> <Unit> at <Temperature> <Unit>

### **Testing proposal** *[IUCLID source: Endpoint summary 5.2.3 Biodegradation in soil]*

**Information requirement:** Soil simulation testing

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Soil type: <Soil type>

Study design: <Details on experimental conditions>

## **4.1.3. Summary and discussion of degradation**

### **Abiotic degradation**

<Discussion> *[IUCLID source: Endpoint summary 5.1 Stability.]*

### **Biotic degradation**

<Discussion> [IUCSID source: Endpoint summary 5.2 Biodegradation.]

## **4.2. Environmental distribution**

### **4.2.1. Adsorption/desorption**

[IUCSID source: section 5.4.1 Adsorption / desorption.  
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The studies on adsorption/desorption are summarised in the following table:

**Table 22. Overview of studies on adsorption/desorption**

<b>Method</b>	<b>Results</b>	<b>Remarks</b>	<b>Reference</b>
Study type: <Study type> (<Media>) <Type of method> <Guideline> <Principles of method if other than guideline>	Adsorption coefficient <Type>: <Value> at <Temperature> <Unit> (Org. C (%): <Org. carbon>) (<Remarks>) Other adsorption coefficients: <Type>: <Value> at <Temperature> <Unit> (<Remarks>) Mass balance (in %) at end of adsorption phase: <% adsorption> after <Duration> (<Sample No.>) Mass balance (in %) at end of desorption phase: <% desorption> after <Duration> (<Sample No.>)	<Reliability> <Purpose flag> <Study result type> <b>Test material                      identity [See                      description of rules                      in introductory part.]</b>	<Author> <Year>

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **Testing proposal**

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Study type: <Study type> <(Media)>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Type of method: <Type of method>

**Discussion** [IUCLID source: Endpoint summary 5.4.1 Adsorption / desorption.]

<Discussion>

The following information is taken into account for any environmental exposure assessment:

<Short description of key information>

**Value used for CSA:**

Koc at 20°C: <Key value for CSA>

<Type>: <Value> <Unit> at <Temperature> <Unit>

## 4.2.2. Volatilisation

[IUCLID source: section 5.4.2 Henry's Law constant.

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The studies on volatilisation are summarised in the following table:

**Table 23. Overview of studies on volatilisation**

Method	Results	Remarks	Reference
<Principles of method if other than guideline> <Details on methods>	Henry's Law constant H: <H> at <Temp. (°C)> °C and <Atm. press.> <Atm. press., unit> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** Justification for data waiving>

### Testing proposal

**Proposed method:** <Principles of method if other than guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

<Details on methods>

**Discussion** [IUCLID source: Endpoint summary 5.4.2 Henry's Law constant.]

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Discussion>

The following information is taken into account for any environmental exposure assessment:

<Short description of key information>

**Value used for CSA:** Henry's law constant (H): <Key value for CSA> (in Pa m<sup>3</sup>/mol or dimensionless) at <Temperature> <Unit>

### 4.2.3. Distribution modelling

[IUCLID source: section 5.4.3 Distribution modelling.

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The data from distribution modelling studies are summarised in the following table:

**Table 24. Overview of distribution modelling studies**

Method	Results	Remarks	Reference
Media: <Media> <Model> Calculation programme: <Calculation programme> Input data: <Test substance input data>	Percent distribution in media: Air (%): <Air (%)> Water (%): <Water (%)> Soil (%): <Soil (%)> Sediment (%): <Sediment (%)> Susp. sediment (%): <Susp. sediment (%)> Biota (%): <Biota (%)> Aerosol (%): <Aerosol (%)> Other distribution results: <Other distribution results>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### 4.2.4. Summary and discussion of environmental distribution

<Discussion> [IUCLID source: Endpoint summary 5.4 Transport and distribution.]

## 4.3. Bioaccumulation

<Discussion> [IUCLID source: Endpoint summary 5.3 Bioaccumulation.]

### 4.3.1. Aquatic bioaccumulation

[IUCLID source: section 5.3.1 Bioaccumulation: aquatic / sediment.]

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

*Sort rule: (I.) Field "Route of exposure" = (1) "aqueous"; (2) "sediment"; (3) "feed"; (4) "other"; (5) empty; (II.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (III.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (IV.) Field "Study result type" = (1) "experimental result"; (2) "estimated by calculation"; (3) "(Q)SAR"; (4) <> "experimental result" or "estimated by calculation" or "(Q)SAR".]*

The studies on aquatic bioaccumulation are summarised in the following table:

**Table 25. Overview of studies on aquatic bioaccumulation**

Method	Results	Remarks	Reference
<Test organisms (species)> <Route of exposure> (<Water media type>) <Test type> Sediment type: <Type of sediment (if sediment study)> Total exposure / uptake duration: <Total exposure / uptake duration> Total depuration duration: <Total depuration duration> Details of method: <Details on estimation of bioconcentration> <Guideline> <Principles of method if other than guideline>	<Bioaccumulation factor_Type>: <Bioaccumulation factor> <Unit> (<Basis>) (<Time of plateau: <Time of plateau> (<Calculation basis>) (<Remarks>)) Elimination: <Elimination>; <Endpoint>: <Depuration time (DT)> Lipid content: <Lipid content> (<Time point>) (<Remarks>)	<Reliability> <Purpose Flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

#### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **4.3.2. Terrestrial bioaccumulation**

*[IUCLID source: section 5.3.2 Bioaccumulation: terrestrial.]*

*Sort rule: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Study result type" = (1) "experimental result"; (2) "estimated by calculation"; (3) "(Q)SAR"; (4) <> "experimental result" or "estimated by calculation" or "(Q)SAR".]*

The results of terrestrial bioaccumulation studies are summarised in the following table:

**Table 23: Overview of studies on terrestrial bioaccumulation**

Method	Results	Remarks	Reference
<Test organisms (species)> <Guideline> <Principles of method if other than guideline>	<Bioaccumulation factor_Type>: <Bioaccumulation factor> <Unit> (<Basis>) (<Time of plateau: <Time of plateau> (<Calculation basis>) (<Remarks>)) Elimination: <Elimination>; <Endpoint>: <Depuration time	<Reliability> <Purpose Flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

	(DT)> Lipid content: <Lipid content> (<Time point>)> (<Remarks>)	<i>part.]</i>	
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#### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **4.3.3. Summary and discussion of bioaccumulation**

**Aquatic bioaccumulation** *[IUCLID source: Endpoint summary 5.3.1 Bioaccumulation: aquatic / sediment.]*

<Discussion>

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

<Short description of key information>

**Value used for CSA: BCF:** <Key value for CSA> <Unit>

**Terrestrial bioaccumulation** *[IUCLID source: Endpoint summary 5.3.2 Bioaccumulation: terrestrial.]*

<Discussion>

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

<Short description of key information>

**Value used for CSA: BCF:** <Key value for CSA> <Unit>

**Testing proposal** *[IUCLID source: Endpoint summary 5.3.1 Bioaccumulation: aquatic / sediment.]*

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Test organisms (species)>

Compartment / route: <Route of exposure> (<(Water media type)>)

Test type: <Test type>

### **4.4. Secondary poisoning**

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5.3 "Calculation of PNEC<sub>oral</sub> (secondary poisoning)").

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

---

Justification for no PNEC oral derivation: <Justification for (no) PNEC oral derivation> **[If "PNEC oral" = "No potential for bioaccumulation".]**

**[If a PNEC oral is provided, the following default statements are inserted:]**

The PNECoral is <PNEC oral> <Unit> (see CSR chapter 7.5.3 "Calculation of PNECoral (secondary poisoning)").

Justification for PNEC oral derivation: <Justification for (no) PNEC oral derivation>

**Interpretation of the available data with regard to the potential to bio-accumulate in the food chain:**

>>>NOTE (please delete this instruction): As appropriate enter relevant information manually.<<<<

## 5. HUMAN HEALTH HAZARD ASSESSMENT

### 5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

#### Summary and discussion of human information

(Note: The following summary has been extracted from the endpoint summary of IUCLID section 7.10 Exposure related observations in humans. Reference to this summary is made in any endpoint-related "Summary and discussion" of this CSR, if relevant endpoint study records are listed in the respective table "Overview of exposure-related observations on ... in humans. As appropriate, copy any relevant information to the "Summary and discussion" part of the corresponding CSR chapter.)

#### Key information:

<Short description of key information> [IUCLID source: section 7.10 Endpoint summary "Exposure related observations in humans".]

#### Discussion:

<Discussion> [IUCLID source: section 7.10 Endpoint summary "Exposure related observations in humans".]

#### 5.1.1. Non-human information

The results of experimental studies on absorption, metabolism, distribution and elimination are summarised in the following table:

**Table 26. Overview of experimental studies on absorption, metabolism, distribution and elimination**

Method	Results	Remarks	Reference
[IUCLID source: section 7.1.1 Basic toxicokinetics. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) <Sex> <Route of administration> Exposure regime: <Duration and frequency of treatment> Doses/conc.: <Doses / concentrations> <Guideline> <Principles of method if other than guideline>	Main ADME results: <Type>: <Text> Transfer (<Transfer type>): <Transfer type>: <Observation> (Test No.: <Test No.>) Toxicokinetic parameters: <Toxicokinetic parameters>> (Test No.: <Test No.>) Metabolites identified: <Metabolites identified> Details on metabolites: <Details on metabolites> Evaluation of results: <Interpretation of results>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
[IUCLID source: section 7.1.2 Dermal absorption. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) <Sex>	<Absorption in different matrices> Total recovery: <Total recovery> Percutaneous absorption rate: <Absorption (%)> % at <Time point> (<Dose>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Coverage (dermal absorption study): <Type of coverage> <Duration of exposure> Doses/conc.: <Doses / concentrations> <Details on in vitro test system (if applicable)> <Guideline> <Principles of method if other than guideline>		<i>description of rules in introductory part.]</i>	
--	--	--	--

Estimated data on toxicokinetics are summarised in the following table:

**Table 27. Overview of estimated data on toxicokinetics**

Method	Results	Remarks	Reference
<i>[IUCLID source: section 7.1.1 Basic toxicokinetics. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
<Species> <Route of administration> <Principles of method if other than guideline>	Main ADME results: <Type>: <Text> Transfer (<Transfer type>): <Transfer type>: <Observation> (Test No.: <Test No.>) Toxicokinetic parameters: <Toxicokinetic parameters> Evaluation of results: <Interpretation of results>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>
<i>[IUCLID source: section 7.1.2 Dermal absorption. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
<Species> Dermal absorption <Principles of method if other than guideline>	<Absorption in different matrices> Percutaneous absorption rate: <Absorption (%)> % at <Time point> (<Dose>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

## 5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 28. Overview of exposure-related observations on basic toxicokinetics and/or dermal absorption in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption".</i></p> <p><i>Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt;</p> <p>&lt;Type of population&gt;</p> <p>Details on study design: &lt;Details on study design&gt;</p> <p>Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt;</p> <p>&lt;Purpose flag&gt;</p> <p><b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption".</i></p> <p><i>Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt;</p> <p>&lt;Type of population&gt;</p> <p>Details on study design: &lt;Details on study design&gt;</p> <p>Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt;</p> <p>&lt;Purpose flag&gt;</p> <p><b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption".</i></p> <p><i>Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt;</p> <p>&lt;Type of population&gt;</p> <p>Subjects: &lt;Subjects&gt;</p> <p>Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt;</p> <p>Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt;</p> <p>&lt;Purpose flag&gt;</p> <p><b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption".</i></p> <p><i>Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt;</p> <p>Details on study design: &lt;Details on study design&gt;</p> <p>Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt;</p> <p>&lt;Purpose flag&gt;</p> <p><b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>

### 5.1.3. Summary and discussion of toxicokinetics

<Discussion> [IUCALID source: Endpoint summary 7.1 Toxicokinetics, metabolism and distribution.]

#### **Basic toxicokinetics** [IUCALID source: Endpoint summary 7.1.1 Basic toxicokinetics.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

**Value used for CSA:** <Key value for CSA>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)  
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

#### **Dermal absorption** [IUCALID source: Endpoint summary 7.1.2 Dermal absorption]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

**Value used for CSA:** Absorption rate (%): <Key value for CSA>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)  
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

## 5.2. Acute toxicity

### 5.2.1. Non-human information

#### 5.2.1.1. Acute toxicity: oral

[IUCALID source: section 7.2.1 Acute toxicity: oral.  
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".  
Rule for multiple "Effect levels": Capture only LD50 values or, if not available, any other.]

The results of experimental studies are summarised in the following table:

**Table 29. Overview of experimental studies on acute toxicity after oral administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 30. Overview of estimated data on acute toxicity after oral administration**

Method	Results	Remarks	Reference
<Species> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### 5.2.1.2. Acute toxicity: inhalation

[IUCLID source: section 7.2.2 Acute toxicity: inhalation.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".

Rule for multiple "Effect levels": Capture only LC50 values or, if not available, any other.]

The results of experimental studies are summarised in the following table:

**Table 31. Overview of experimental studies on acute toxicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Exp. duration>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 30: Summary of estimated data on acute toxicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species>  <Principles of method if other than guideline>	<Endpoint> (<Exp. duration>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability>  <Purpose flag>  <Study result type>	<Author> <Year>

**Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**5.2.1.3. Acute toxicity: dermal**

*[IUCLID source: section 7.2.3 Acute toxicity: dermal.*

*Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".*

*Rule for multiple "Effect levels": Capture only LD50 values or, if not available, any other.]*

The results of estimated data on acute toxicity after dermal administration are summarised in the following table:

**Table 32. Overview of estimated data on acute toxicity after dermal administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> Coverage: <Type of coverage> Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability>  <Purpose flag>  <Study result type>	<Author> <Year>

Estimated data are summarised in the following table:

**Table 32: Overview of estimated data on acute toxicity after dermal administration**

Method	Results	Remarks	Reference
<Species>  <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability>  <Purpose flag>  <Study result type>	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### **5.2.1.4. Acute toxicity: other routes**

[IUCLID source: section 7.2.4 Acute toxicity: other routes.

Sort rule in table: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".]

The results of studies on acute toxicity (other routes) are summarised in the following table:

**Table 33: Overview of studies on acute toxicity (other routes)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### **5.2.2. Human information**

The exposure-related observations in humans are summarised in the following table:

**Table 33. Overview of exposure-related observations on acute toxicity in humans**

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "acute toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "acute toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Study type> <Type of population>	<Results>	<Reliability> <Purpose flag>	<Author> <Year>

EC number: <Chemical name> CAS number:  
 <EC number> <CAS number>

Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>		<b>Test material identity</b> [See description of rules in introductory part.]	
<i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "acute toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "acute toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### 5.2.3. Summary and discussion of acute toxicity

*[IUCLID source: Endpoint summary 7.2 Acute toxicity.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

#### Value used for CSA:

<Effect level> (oral): <Key value for CSA> mg/kg bw

<Effect level> (dermal): <Key value for CSA> mg/kg bw

<Effect level> (inhalation): <Key value for CSA> mg/kg bw

#### Justification for classification or non classification

<Justification for classification or non-classification>

#### Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

*[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the*

overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

## 5.3. Irritation

### 5.3.1. Skin

#### 5.3.1.1. Non-human information

[IUCLID source: section 7.3.1 Skin irritation / corrosion.

Rule: Insert if field "Study result type" <> "(Q)SAR" and <> "estimated by calculation" AND field "Interpretation of results" <> "corrosive\*", "highly corrosive\*", "Category 1 (corrosive)\*", "Category IA (corrosive)\*", "Category IB (corrosive)\*", "Category IC (corrosive)\*", "Category I\*".  
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".  
Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "primary dermal irritation index (PDII)"; (3) "erythema score"; (4) "edema score".]

The results of experimental studies on skin irritation are summarised in the following table:

**Table 34. Overview of experimental studies on skin irritation**

Method	Results	Remarks	Reference
in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) Coverage: <Type of coverage> (<Preparation of test site>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Primary dermal irritation index (PDII): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Erythema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Edema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 35. Overview of estimated data on skin irritation**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline>	<Interpretation of results>	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity. *[Insert if field "Interpretation of results" = "corrosive\*", "highly corrosive\*", "Category I (corrosive)\*", "Category IA (corrosive)\*", "Category IB (corrosive)\*", "Category IC (corrosive)\*", "Category I\*".]*

**Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**5.3.1.2. Human information**

The exposure-related observations in humans are summarised in the following table:

**Table 36. Overview of exposure-related observations on skin irritation in humans**

Method	Results	Remarks	Reference
<i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>
<i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>
<i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material</b>	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>		<b>identity</b> [See description of rules in introductory part.]	
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

## 5.3.2. Eye

### 5.3.2.1. Non-human information

[IUCLID source: section 7.3.2 Eye irritation.

Rule: Insert if field "Study result type" <> "(Q)SAR" and <> "estimated by calculation" AND field "Interpretation of results" <> "corrosive\*", "highly corrosive\*", "Category I\*" or "Category I\*".

Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "Maximum mean total score (MMTS)"; (3) "cornea score"; (4) "iris score"; (5) "conjunctivae score"; (6) "chemosis score".]

The results of experimental studies on eye irritation are summarised in the following table:

**Table 37. Overview of experimental studies on eye irritation**

Method	Results	Remarks	Reference
in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Maximum mean total score (MMTS): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Cornea score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Iris score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Conjunctivae score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>



EC number: <EC number> <Chemical name> CAS number: <CAS number>

Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### 5.3.3. Respiratory tract

#### 5.3.3.1. Non-human information

#### 5.3.3.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 41: Overview of exposure-related observations on respiratory irritation in humans**

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "respiratory irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

study design> Endpoint addressed: <Endpoint addressed>		<i>in introductory part.</i>	
<i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "respiratory irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "respiratory irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "respiratory irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### 5.3.4. Summary and discussion of irritation

*[IUCLID source: Endpoint summary 7.3 Irritation / corrosion.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

#### Value used for CSA:

Skin irritation / corrosion: <Key value for CSA>

Eye irritation: <Key value for CSA>

Respiratory irritation: <Key value for CSA>

### **Justification for classification or non classification**

<Justification for classification or non-classification>

#### **Discussion of human information:**

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

*[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]*

## **5.4. Corrosivity**

### **5.4.1. Non-human information**

*[IUCLID source: sections 7.3.1 Skin irritation / corrosion.*

*Rule: Insert if field "Study result type" <> "(Q)SAR" and <> "estimated by calculation" AND field "Interpretation of results" = "corrosive\*", "highly corrosive\*", "Category 1 (corrosive)\*", "Category IA (corrosive)\*", "Category 1B (corrosive)\*", "Category 1C (corrosive)\*", "Category 1\*".*

*Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".*

*Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "primary dermal irritation index (PDII)"; (3) "erythema score"; (4) "edema score".]*

*[IUCLID source: section 7.3.2 Eye irritation.*

*Rule: Insert if field "Study result type" <> "(Q)SAR" and <> "estimated by calculation" AND field "Interpretation of results" = "corrosive\*", "highly corrosive\*", "Category 1\*" or "Category I\*".*

*Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".*

*Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "Maximum mean total score (MMTS)"; (3) "cornea score"; (4) "iris score"; (5) "conjunctivae score"; (6) "chemosis score".]*

The results of experimental studies on skin and eye irritation related to corrosivity are summarised in the following table:

**Table 40. Overview of experimental studies on skin and eye irritation related to corrosivity**

Method	Results	Remarks	Reference
<b>[IUCLID source: section 7.3.1 Skin irritation / corrosion.]</b>			
Tissue studied: skin in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) Coverage: <Type of coverage> (<Preparation of test site>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Primary dermal irritation index (PDII): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Erythema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Edema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material            identity [See            description of rules            in introductory part.]</b>	<Author> <Year>
<b>[IUCLID source: section 7.3.2 Eye irritation.]</b>			
Tissue studied: eye in vitro study [If field "Type of method" = "in vitro".] <Species> (<Strain>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Maximum mean total score (MMTS): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Cornea score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Iris score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Conjunctivae score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Chemosis score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material            identity [See            description of rules            in introductory part.]</b>	<Author> <Year>

EC number: <Chemical name> CAS number:  
 <EC number> <CAS number>

	<Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)		
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Estimated data are summarised in the following table:

**Table 41. Overview of estimated data on skin and eye irritation related to corrosivity**

Method	Results	Remarks	Reference
<b>[IUCLID source: section 7.3.1 Skin irritation / corrosion.]</b>			
Model based on: skin <Guideline> <Principles of method if other than guideline>	<Interpretation of results>	<Reliability> <Purpose flag>	<Author> <Year>
<b>[IUCLID source: section 7.3.2 Eye irritation.]</b>			
Model based on: eye <Guideline> <Principles of method if other than guideline>	<Interpretation of results>	<Reliability> <Purpose flag>	<Author> <Year>

## 5.4.2. Human information

### 5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation. **[Insert if field "Interpretation of results" = "corrosive\*", "highly corrosive\*", "Category I (corrosive)\*", "Category IA (corrosive)\*", "Category IB (corrosive)\*", "Category IC (corrosive)\*", "Category I\*", "Category I\*".]**

## 5.5. Sensitisation

### 5.5.1. Skin

#### 5.5.1.1. Non-human information

**[IUCLID source: sections 7.3.1 Skin irritation / corrosion.**  
**Sort rule in tables: (I.) Field "Type of study" = (1) "Mouse local lymphnode assay (LLNA)"; (2) <> "Mouse local lymphnode assay (LLNA)"; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]**

The results of experimental studies on skin sensitisation are summarised in the following table:

**Table 42. Overview of experimental studies on skin sensitisation**

Method	Results	Remarks	Reference
in vitro study <Species> (<Strain>) <Sex> Local lymph node assay <Type of study> Induction: <Route of induction exposure> Challenge: <Route of challenge exposure> Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Stimulation index: <Stimulation index> No. with positive reactions: <Reading>: <No. with + reactions> out of <Total no. in group> (<Group>; <Hours after challenge> h after chall.; dose: <Dose level>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

Estimated data are summarised in the following table:

**Table 43. Summary of estimated data on skin sensitisation**

Method	Results	Remarks	Reference
Model based on: <Type of study> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Stimulation index: <Stimulation index>	<Reliability> <Purpose flag>	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### 5.5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 44. Overview of exposure-related observations on skin sensitisation in humans**

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.4 Sensitisation data (humans), if "Type of sensitisation studied" = "skin". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
Study type: <Study type> Type of population: <Type of population> Subjects: <Subjects>	<Results>	<Reliability> <Purpose flag> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "skin sensitisation".]			

<b>Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</b>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<b>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</b>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<b>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</b>			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<b>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</b>			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

## 5.5.2. Respiratory system

### 5.5.2.1. Non-human information

**[IUCLID source: section 7.4.2 Respiratory sensitisation. Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]**

The results of experimental studies on respiratory sensitisation are summarised in the following table:

**Table 45. Overview of experimental studies on respiratory sensitisation respiratory sensitisation**

Method	Results	Remarks	Reference
in vitro study [ <i>If field "Type of method" = "in vitro".</i> ] <Species> (<Strain>) <Sex> Induction: <Route of induction exposure> Challenge: <Route of challenge exposure> Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> <Results>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [ <i>See description of rules in introductory part.</i> ]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 46. Overview of estimated data on respiratory sensitisation**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline>	<Interpretation of results> <Results>	<Reliability> <Purpose flag>	<Author> <Year>

### 5.5.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 47. Overview of exposure-related observations on skin sensitisation in humans**

Method	Results	Remarks	Reference
[ <i>IUCLID source: section 7.10.4 Sensitisation data (humans), if "Type of sensitisation studied" = "respiratory". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".</i> ]			
Study type: <Study type> Type of population: <Type of population> Subjects: <Subjects>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [ <i>See description of rules in introductory part.</i> ]	<Author> <Year>
[ <i>IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".</i> ]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed:	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [ <i>See description of rules in introductory part.</i> ]	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Endpoint addressed>			
<i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
<i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### 5.5.3. Summary and discussion of sensitisation

**Skin sensitisation** *[IUCLID source: Endpoint summary 7.4 Sensitisation: Skin sensitisation.]*

<Skin sensitisation, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Skin sensitisation, Short description of key information>

**Value used for CSA:** <Key value for CSA>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

*[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]*

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Respiratory sensitisation** [IUCLID source: Endpoint summary 7.4 Sensitisation: Respiratory sensitisation.]

<Respiratory sensitisation, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Respiratory sensitisation, Short description of key information>

**Value used for CSA:** <Key value for CSA>

**Discussion of human information:**

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)  
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

**Justification for classification or non classification** [IUCLID source: Endpoint summary 7.4 Sensitisation.]

<Justification for classification or non-classification>

## 5.6. Repeated dose toxicity

### 5.6.1. Non-human information

#### 5.6.1.1. Repeated dose toxicity: oral

[IUCLID source: section 7.5.1 Repeated dose toxicity: oral.  
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".  
Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL identified"; (2) "NOAEL"; (3) "NOEL"; (4) "LOAEL"; (5) "LOEL"; (6) "BMD05"; (7) "BMD10"; (8) "BMD:" ; (9) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 48. Overview of experimental studies on repeated dose toxicity after oral administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>; <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 49. Overview of estimated data on repeated dose toxicity after oral administration**

Method	Results	Remarks	Reference
<Species> <Test type> (<Route of administration>) <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

### **Data waiving**

**Information requirement (Test type):** short-term toxicity study (28 days) / sub-chronic toxicity study (90 days) / <Test type> [If <Test type> = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **5.6.1.2. Repeated dose toxicity: inhalation**

[IUCLID source: section 7.5.3 Repeated dose toxicity: inhalation.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) "mouse"; (3) "dog"; (4) <> "rat" or "mouse" or "dog".

Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL/C identified"; (2) "NOAEL/C"; (3) "NOEL/C"; (4) "LOAEL/C"; (5) "LOEL/C"; (6) "BMD/C05"; (7) "BMD/C10"; (8) "BMD/C:"; (9) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 50. Overview of experimental studies on repeated dose toxicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) (<Type of inhalation exposure>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 51. Overview of estimated data on repeated dose toxicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species> <Test type> (<Route of administration>) <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

### **Data waiving**

**Information requirement (Test type):** short-term toxicity study (28 days) / sub-chronic toxicity study (90 days) / <Test type> [If <Test type> = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **5.6.1.3. Repeated dose toxicity: dermal**

[IUCALD source: section 7.5.2 Repeated dose toxicity: dermal.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".

Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL identified"; (2) "NOAEL"; (3) "NOEL"; (4) "LOAEL"; (5) "LOEL"; (6) "BMD05"; (7) "BMD10"; (8) "BMD:" ; (9) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 52. Overview of experimental studies on repeated dose toxicity after dermal administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> Coverage: <Type of coverage> <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 53. Overview of estimated data on repeated dose toxicity after dermal administration**

Method	Results	Remarks	Reference
<Species> <Test type> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type>	<Author> <Year>

### Data waiving

**Information requirement (Test type):** short-term toxicity study (28 days) / sub-chronic toxicity study (90 days) / <Test type> [If <Test type> = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### 5.6.1.4. Repeated dose toxicity: other routes

[IUCLID source: section 7.5.4 Repeated dose toxicity: other routes.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".

Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL/C identified"; (2) "NOAEL/C"; (3) "NOEL/C"; (4) "LOAEL/C"; (5) "LOEL/C"; (6) "BMD/C05"; (7) "BMD/C10"; (8) "BMD/C:"; (9) any other or empty.]

The results of studies on repeated dose toxicity (other routes) are summarised in the following table:

**Table 54. Overview of experimental studies on repeated dose toxicity (other routes)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

## 5.6.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 55. Overview of exposure-related observations on repeated dose toxicity in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "repeated dose toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "repeated dose toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "repeated dose toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "repeated dose toxicity:*". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>

### 5.6.3. Summary and discussion of repeated dose toxicity

#### **Testing proposal**

[IUCLID source: section 7.5.1 / 7.5.2 / 7.5.3 Repeated dose toxicity: oral / dermal / inhalation.]

**Information requirement (Test type):** short-term toxicity study (28 days) (oral/dermal/inhalation) / sub-chronic toxicity study (90 days) (oral/dermal/inhalation) / chronic toxicity study (oral/dermal/inhalation) <Test type> (oral/dermal/inhalation) [If <Test type> = "subacute" / = "subchronic" / = "chronic" / <> "subacute" or "subchronic" or "chronic".]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Species> (<Strain>) <Sex>

**Discussion** [IUCLID source: Endpoint summary 7.5 Repeated dose toxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

**Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit> (<Test type>; <Species>)

Target organs: <Target organ>

**Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit> (<Test type>; <Species>)

Target organs: <Target organ>

**Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit> (<Test type>; <Species>)

Target organs: <Target organ>

**Justification for classification or non classification**

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

## 5.7. Mutagenicity

### 5.7.1. Non-human information

#### 5.7.1.1. In vitro data

[IUCLID source: section 7.6.1 Genetic toxicity in vitro.]

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Sort rule in tables: (I.) Field "Type of genotoxicity" = (1) "gene mutation"; (2) = "chromosome aberration"; (3) = "DNA damage and/or repair"; (4) = "genome mutation"; (5) = "other:" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results of experimental studies are summarised in the following table:

**Table 56. Overview of experimental in vitro genotoxicity studies**

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>)  <Species/strain> (Met. act.: <Metabolic activation>)  Doses: <Test concentrations>  <Guideline>  <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results>  Test results: <Genotoxicity> for <Species/strain> (<Test system>); met. act.: <Metabolic activation>; cytotoxicity: <Cytotoxicity>	<Reliability>  <Purpose flag>  <Study result type>  <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 57. Overview of experimental in vitro genotoxicity studies**

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>)  <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results>	<Reliability>  <Purpose flag>  <Study result type>  <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Information requirement (Test type):** <Type of study> (<Type of genotoxicity>)

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### 5.7.1.2. In vivo data

[IUCLID source: section 7.6.2 Genetic toxicity in vivo.]

Sort rule in tables: (I.) Field "Type of genotoxicity" = (1) "gene mutation"; (2) = "chromosome aberration"; (3) = "DNA damage and/or repair"; (4) = "genome mutation"; (5) = "other:" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results of experimental studies are summarised in the following table:

**Table 58. Overview of experimental in vivo genotoxicity studies**

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>) <Species> (<Strain>) <Sex> <Route of administration> Doses: <Doses / concentrations> <Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results>  Genotoxicity: <Genotoxicity> (<Sex>); toxicity: <Toxicity>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 59. Overview of experimental in vivo genotoxicity studies**

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>)  <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Information requirement (Test type):** <Type of study> (<Type of genotoxicity>)

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

## 5.7.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 60. Overview of exposure-related observations genetic toxicity in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>

### 5.7.3. Summary and discussion of mutagenicity

**Testing proposal** [IUCLID source: sections 7.6.1 Genetic toxicity in vitro / 7.6.2 Genetic toxicity in vivo.]

**Information requirement (Test type):** in vitro: <Type of study> (<Type of genotoxicity>) / in vivo <Type of study> (<Type of genotoxicity>) [If record in section 7.6.1 / 7.6.2, respectively.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

**Discussion** [IUCLID source: Endpoint summary 7.6 Genetic toxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

**Value used for CSA:** Genetic toxicity: <Key value for CSA>

**Justification for classification or non classification**

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

## 5.8. Carcinogenicity

### 5.8.1. Non-human information

#### 5.8.1.1. Carcinogenicity: oral

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "oral: ...").  
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".  
Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

The results of experimental studies are summarised in the following table:

**Table 61. Overview of experimental studies on carcinogenicity after oral administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> [If "oral: *", but <> "oral: unspecified"] <Doses / concentrations> (<Basis>)	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	Neoplastic effects: <Histopathology: neoplastic>	<i>description of rules in introductory part.]</i>	
--	---	--	--

Estimated data are summarised in the following table:

**Table 62. Overview of estimated studies on carcinogenicity after oral administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <i>[If "oral:*" , but &lt;&gt; "oral: unspecified"]</i> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>

### 5.8.1.2. Carcinogenicity: inhalation

*[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "inhalation: ...").  
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".  
Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]*

The results of experimental studies are summarised in the following table:

**Table 63. Overview of experimental studies on carcinogenicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>

Estimated data are summarised in the following table:

**Table 64. Overview of estimated studies on carcinogenicity after inhalation exposure**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

### 5.8.1.3. Carcinogenicity: dermal

[IUCLLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "dermal").  
 Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".  
 Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

The results of experimental studies are summarised in the following table:

**Table 65. Overview of experimental studies on carcinogenicity after dermal administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

Estimated data are summarised in the following table:

**Table 66. Overview of estimated studies on carcinogenicity after dermal administration**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

EC number: <EC number>	<Chemical name>	CAS number: <CAS number>
guideline>		

#### 5.8.1.4. Carcinogenicity: other routes

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" <> "oral:..." or "inhalation:..." or "dermal").

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".

Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

The results of experimental studies are summarised in the following table:

**Table 67. Overview of experimental studies carcinogenicity (other routes)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 68. Overview of estimated studies carcinogenicity (other routes)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

## 5.8.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 69. Overview of exposure-related observations on carcinogenicity in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>

### 5.8.3. Summary and discussion of carcinogenicity

**Data waiving** [IUCLID source: sections 7.7 Carcinogenicity.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Testing proposal** [IUCLID source: sections 7.7 Carcinogenicity.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Species> (<Strain>) <Sex>

**Discussion** [IUCLID source: Endpoint summary 7.7 Carcinogenicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

**Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit>

Target organs for carcinogenicity: <Target organ>

**Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit>

Target organs for carcinogenicity: <Target organ>

**Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit>

Target organs for carcinogenicity: <Target organ>

**Justification for classification or non classification**

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

## 5.9. Toxicity for reproduction

### 5.9.1. Effects on fertility

#### 5.9.1.1. Non-human information

[IUCLID source: section 7.8.1 Toxicity to reproduction.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 70. Overview of experimental studies on fertility**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 71. Overview of estimated studies on fertility**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Toxicity to reproduction: other studies**

[IUCLID source: section 7.8.3 Toxicity to reproduction: other studies.

Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study"; (II.) Field "Species" = (1) "rat"; (2) = "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 72. Overview of experimental studies on the toxicity to reproduction (other studies)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 73. Overview of estimated studies on the toxicity to reproduction (other studies)**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### 5.9.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 74. Overview of exposure-related observations on toxicity to reproduction / fertility in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "toxicity to reproduction / fertility". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "toxicity to reproduction / fertility". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "toxicity to reproduction / fertility". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "toxicity to reproduction / fertility". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>

## 5.9.2. Developmental toxicity

### 5.9.2.1. Non-human information

[IUCLID source: section 7.8.2 Developmental toxicity / teratogenicity.  
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study";  
(II.) Field "Species" = (1) "rat"; (2) = "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

The results of experimental studies are summarised in the following table:

**Table 75. Overview of experimental studies on developmental toxicity**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 76. Overview of estimated studies on developmental toxicity**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### 5.9.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 77. Overview of exposure-related observations on the developmental toxicity in humans**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "developmental toxicity / teratogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "developmental toxicity / teratogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "developmental toxicity / teratogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "developmental toxicity / teratogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>

### 5.9.3. Summary and discussion of reproductive toxicity

**Testing proposal** [IUCLID source: sections 7.8.1 Toxicity to reproduction / 7.8.2 Developmental toxicity / teratogenicity.]

**Information requirement:** in vitro: Toxicity for reproduction / Developmental toxicity / teratogenicity [If record in section 7.8.1 / 7.8.2, respectively.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

**Discussion** [IUCLID source: Endpoint summary 7.8 Toxicity to reproduction.]

#### **Effects on fertility**

<Effects on fertility, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Effects on fertility, Short description of key information>

**Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit>

**Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit>

**Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

#### **Developmental toxicity**

<Developmental toxicity / teratogenicity, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Developmental toxicity / teratogenicity, Short description of key information>

**Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit>

**Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit>

**Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

#### Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

#### Toxicity to reproduction: other studies

<Toxicity to reproduction: other studies, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Toxicity to reproduction: other studies, Short description of key information>

#### Justification for classification or non classification

<Justification for classification or non-classification>

## 5.10. Other effects

### 5.10.1. Non-human information

#### 5.10.1.1. Neurotoxicity

[IUCLID source: section 7.9.1 Neurotoxicity.

Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results of experimental studies are summarised in the following table:

**Table 78. Overview of experimental studies on neurotoxicity**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation (if applicable)>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 79. Overview of estimated studies on neurotoxicity**

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>)	<Endpoint> (<Generation (if applicable)>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material</b>	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>		<b>identity</b> [See description of rules in introductory part.]	
--	--	--	--

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **5.10.1.2. Immunotoxicity**

[IUCLID source: section 7.9.2 Immunotoxicity.

Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results of experimental studies are summarised in the following table:

**Table 80. Overview of experimental studies on immunotoxicity**

<b>Method</b>	<b>Results</b>	<b>Remarks</b>	<b>Reference</b>
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 81. Overview of estimated studies on immunotoxicity**

<b>Method</b>	<b>Results</b>	<b>Remarks</b>	<b>Reference</b>
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>)	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

EC number: <EC number>	<Chemical name>	CAS number: <CAS number>
<Guideline> <Principles of method if other than guideline>		

### 5.10.1.3. Specific investigations: other studies

[IUCLID source: section 7.9.3 Specific investigations: other studies.  
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results of experimental studies are summarised in the following table:

**Table 82. Overview of specific investigations: other experimental studies**

Method	Results	Remarks	Reference
Endpoint addressed: <Endpoint addressed> Type of effects studied: <Type of effects studied> (<Type of method>) <Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Details on results>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Estimated data are summarised in the following table:

**Table 83. Overview of specific investigations: other estimated studies**

Method	Results	Remarks	Reference
Endpoint addressed: <Endpoint addressed> Type of effects studied: <Type of effects studied> (<Type of method>) <Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Details on results>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

## 5.10.2. Human information

The exposure-related observations in humans are summarised in the following table:

**Table 84. Overview of exposure-related observations on neurotoxicity**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>

**Table 85. Overview of exposure-related observations on immunotoxicity**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "immunotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "immunotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "immunotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "immunotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> <i>[See description of rules in introductory part.]</i></p>	<Author> <Year>

**Table 86. Overview of exposure-related observations: endpoint not specified**

Method	Results	Remarks	Reference
<p><i>[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "not applicable" or empty. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "not applicable" or empty. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "not applicable" or empty. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Study type&gt; &lt;Type of population&gt; Subjects: &lt;Subjects&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<p>&lt;Results of examinations&gt; Outcome of incidence: &lt;Outcome of incidence&gt;</p>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>
<p><i>[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "not applicable" or empty. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i></p>			
<p>Study type: &lt;Type of information&gt; Details on study design: &lt;Details on study design&gt; Endpoint addressed: &lt;Endpoint addressed&gt;</p>	<Results>	<p>&lt;Reliability&gt; &lt;Purpose flag&gt; <b>Test material identity</b> [See description of rules in introductory part.]</p>	<Author> <Year>

### 5.10.3. Summary and discussion of specific investigations

#### **Neurotoxicity** [IUCLID source: Endpoint summary 7.9.1 Neurotoxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

#### **Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit>

#### **Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit>

#### **Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit>

#### **Justification for classification or non classification**

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

#### **Immunotoxicity** [IUCLID source: Endpoint summary 7.9.2 Immunotoxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

#### **Value used for CSA (route: oral):**

<Effect level>: <Key value for CSA> <Unit>

#### **Value used for CSA (route: dermal):**

<Effect level>: <Key value for CSA> <Unit>

#### **Value used for CSA (route: inhalation):**

<Effect level>: <Key value for CSA> <Unit>

#### **Justification for classification or non classification**

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)

[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

*overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]*

**Specific investigations: other studies** *[IUCLID source: Endpoint summary 7.9.3 Specific investigations: other studies.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

## 5.11. Derivation of DNEL(s) / DMEL(s)

### 5.11.1. Overview of typical dose descriptors for all endpoints

**Table 87. Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment.**

*[IUCLID source: 7 Endpoint summary "Toxicological information". Note: In the real CSR documents, the table is formatted in landscape and larger font size.]*

Endpoint		Dose descriptor	Qualitative assessment	Remarks on study
Acute toxicity	oral	<Effect level>: <Value> mg/kg bw e.g. LD50: 20 mg/kg bw		<Short description of key information>
Acute toxicity	dermal	<Effect level>: <Value> mg/kg bw		
Acute toxicity	inhalation	<Effect level>: <Value> mg/kg bw		
Irritation / Corrosivity	skin		<Key value> e.g. highly irritating	<Short description of key information>
Irritation / Corrosivity	eye		<Key value>	
Irritation / Corrosivity	resp. tract		<Key value>	
Sensitisation	skin		<Key value>	<Short description of key information>
Sensitisation	resp. tract		<Key value>	
Repeated dose toxicity: sub-acute/ sub-chronic/ chronic	oral	<Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>  e.g. NOAEL: 12 mg/kg bw/day (chronic; rat) Target organs: cardiovascular / hematological: spleen		<Short description of key information>
Repeated dose toxicity: sub-acute/ sub-chronic/ chronic	dermal	<Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>		
Repeated dose toxicity: sub-	inhalation	<Effect level>: <Value> <Unit> (<Test type>;		

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Endpoint		Dose descriptor	Qualitative assessment	Remarks on study
acute/ sub-chronic/ chronic		<Species> Target organs: <Target organ>		
Mutagenicity	in vitro / in vivo		<Key value>	<Short description of key information>
Carcinogenicity	oral	<Effect level>: <Value> <Unit> Target organs for carcinogenicity: <Target organ>		<Short description of key information>
Carcinogenicity	dermal	<Effect level>: <Value> <Unit> Target organs for carcinogenicity: <Target organ>		
Carcinogenicity	inhalation	<Effect level>: <Value> <Unit> Target organs for carcinogenicity: <Target organ>		
Reproductive toxicity: fertility impairment	oral	<Effect level>: <Value> <Unit>		
Reproductive toxicity: fertility impairment	dermal	<Effect level>: <Value> <Unit>		<Short description of key information>
Reproductive toxicity: fertility impairment	inhalation	<Effect level>: <Value> <Unit>		
Reproductive toxicity: developmental toxicity	oral	<Effect level>: <Value> <Unit>		
Reproductive toxicity: developmental toxicity	dermal	<Effect level>: <Value> <Unit>		<Short description of key information>
Reproductive toxicity: developmental toxicity	inhalation	<Effect level>: <Value> <Unit>		

## 5.11.2. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects

**Table 88. DN(M)ELs for workers**

[IUCLID source: Endpoint summary 7. Toxicological information. Note: In the real CSR documents, the table is formatted in landscape and larger font size.]

$f(\text{<DN(M)EL value>} * \text{<AF>})$  means that the dose descriptor is calculated by multiplying the values from two specified fields. Note that some rounding imprecision may occur if the original dose descriptor value reported in the endpoint summary of section 7 has been rounded. For instance: Original NOAEL: 3.8 divided by AF 15 = DNEL 0.2533, rounded to 0.25. Derived NOAEL: DNEL 0.25 multiplied by AF 15 = 3.75.]

Exposure pattern	Route	Descriptor	DNEL / DMEL *)	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	<DN(M)EL (type)>	<DN(M)EL value> <Unit> e.g. 12 mg/kg bw/day	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>) e.g. NOAEL: 120 mg/kg bw/day (based on AF of 10)	<Most sensitive endpoint> e.g. acute toxicity	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Acute - local effects	Dermal	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Long-term - systemic effects	Dermal	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Long-term - local effects	Dermal	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DN(M)EL (type)>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: $f(\text{<DN(M)EL value>} * \text{<AF>})$ <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>

\*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "AF" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of AFs.

**Discussion**

<Results and discussions, Workers, Discussion>

**Table 89. DN(M)ELs for the general population**

[IUCLID source: Endpoint summary 7. Toxicological information. Note: In the real CSR documents, the table is formatted in landscape and larger font size.]

f(<DN(M)EL value> \* <AF>) means that the dose descriptor is calculated by multiplying the values from two specified fields. Note that some rounding imprecision may occur if the original dose descriptor value reported in the endpoint summary of section 7 has been rounded. For instance: Original NOAEL: 3.8 divided by AF 15 = DNEL 0.2533, rounded to 0.25. Derived NOAEL: DNEL 0.25 multiplied by AF 15 = 3.75.]

Exposure pattern	Route	Descriptor	DNEL / DMEL *)	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	<DNEL>	<DN(M)EL value> <Unit> e.g. 12 mg/kg bw/day	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)  e.g. NOAEL: 120 mg/kg bw/day (based on AF of 10)	<Most sensitive endpoint>  e.g. acute toxicity	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Oral	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Acute - local effects	Dermal	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Long-term - systemic effects	Dermal	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Inhalation	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
	Oral	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
Long-term - local effects	Dermal	<DNEL>	<DN(M)EL value> <Unit>	<Dose descriptor starting point>: f(<DN(M)EL value> * <AF>) <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

	Inhalation	<DNEL>	<DN(M)EL value> <Unit>	<AF> <Dose descriptor starting point>: f<DN(M)EL value> * <AF> <Unit> (based on AF of <AF>)	<Most sensitive endpoint>	<Justification for (no) DN(M)EL derivation / applied AFs>
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\*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "AF" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of AFs.

### Discussion

<General population, Discussion>

## 6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

### 6.1. Explosivity

[IUCLID source: section 4.14 Explosiveness.

Sort rule in table: (1.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study". Note: The placeholder for field "Remarks on results including tables" (now labelled "Any other information on results incl. tables") has been removed because this is a rich text field and it turned out that long text and tables entered in this field would make this CSR table unreadable.]

The available information on flammability is summarised in the following table:

**Table 90. Overview of information on explosivity**

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> Study results: Explosive under influence of flame: <Explosive under influence of flame> More sensitive to shock than m-dinitrobenzene: <More sensitive to shock than m-dinitrobenzene> More sensitive to friction than m-dinitrobenzene: <More sensitive to friction than m-dinitrobenzene> Explosive (not specified): <Explosive (not specified)> Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Data waiving: see CSR section 1.3 Physico-chemical properties. [Insert if field "Data waiving" is populated in any record.]

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Discussion> [IUCLID source: Endpoint summary 4.14 Explosiveness.]

The following information is taken into account for any hazard / risk assessment:

<Short description of key information> [IUCLID source: Endpoint summary 4.14 Explosiveness.]

**Classification according to GHS:** [IUCLID source: section 2.1 GHS.]

**Name:** <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

**Classification according to DSD / DPD**

**Classification status:** <Status> <(Name)> [IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]

<Explosiveness>

**Reason for no classification:** <Reason for no classification>

**Justification for classification or non-classification:** <Justification for classification or non-classification>

## 6.2. Flammability

[IUCLID source: section 4.13 Flammability / 4.11 Flash point.

Note: The placeholder for field "Remarks on results including tables" (now labelled "Any other information on results incl. tables") has been removed because this is a rich text field and it turned out that long text and tables entered in this field would make this CSR table unreadable.]

The available information on flammability is summarised in the following table:

**Table 91. Overview of information on flammability**

Method	Results	Remarks	Reference
[IUCLID source: section 4.13 Flammability. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]			
<Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results>  Study results:  Ignition on contact with air: <Solid/liquid: Ignition on contact with air> (<Remarks>)  Burning time (s): <Solid: Burning time (s)> (<Remarks>)  Flame extension (cm): <Aerosol: Flame extension (cm)> (<Remarks>)  Flame projection (cm): <Aerosol: Flame projection (cm)> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

EC number: <Chemical name> CAS number:  
 <EC number> <CAS number>

	Lower explosion limit (%): <Gas: Lower explosion limit (%)> (<Remarks>)  Upper explosion limit (%): <Gas: Upper explosion limit (%)> (<Remarks>)  Remarks:  <Any other information on results incl. tables>		
<i>[IUCLID source: section 4.11 Flash point.          Sort rule: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]</i>			
Determination of flash point <Type of method> <Guideline> <Principles of method if other than guideline>	Flash point: <Flash point> at <Pressure> (<Remarks>)  Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>

Data waiving: see CSR section 1.3 Physico-chemical properties. *[Insert if field "Data waiving" is populated in any record.]*

<Discussion> *[IUCLID source: Endpoint summary 4.13 Flammability.]*

The following information is taken into account for any hazard / risk assessment:

<Short description of key information> *[IUCLID source: Endpoint summary 4.13 Flammability.]*

### **Flash point**

Data waiving: see CSR section 1.3 Physico-chemical properties. *[Insert if field "Data waiving" is populated in any record.]*

<Discussion> *[IUCLID source: Endpoint summary 4.11 Flash point.]*

The following information is taken into account for any hazard / risk assessment:

<Short description of key information> *[IUCLID source: Endpoint summary 4.11 Flash point.]*

### **Classification according to GHS:** *[IUCLID source: section 2.1 GHS.]*

Name: <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

### **Classification according to DSD / DPD**

Classification status: <Status> <(Name)> *[IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]*

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Flammability>

**Reason for no classification:** <Reason for no classification> [Inserted if field "Reason for no classification" is populated AND "Status" <> "67/548/EEC annex 1".]

**Justification for classification or non-classification:** <Justification for classification or non-classification>

### 6.3. Oxidising potential

[IUCLID source: section 4.15 Oxidising properties.]

Sort rule in table: (1.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".  
Note: The placeholder for field "Remarks on results including tables" (now labelled "Any other information on results incl. tables") has been removed because this is a rich text field and it turned out that long text and tables entered in this field would make this CSR table unreadable.]

The available information on the oxidising potential is summarised in the following table:

**Table 92. Overview of information on oxidising potential**

Method	Results	Remarks	Reference
Contact with: <Contact with> (<Duration of test (contact time)>) <Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> <Test result, result>: <Test result, range> (<Remarks>) Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

Data waiving: see CSR section 1.3 Physico-chemical properties. [Insert if field "Data waiving" is populated in any record.]

<Discussion> [IUCLID source: Endpoint summary 4.15 Oxidising properties.]

The following information is taken into account for any hazard / risk assessment:

<Short description of key information> [IUCLID source: Endpoint summary 4.15 Oxidising properties.]

**Classification according to GHS:** [IUCLID source: section 2.1 GHS.]

**Name:** <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

#### **Classification according to DSD / DPD**

**Classification status:** <Status> <(Name)> [IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]

<Flammability>

**Reason for no classification:** <Reason for no classification> [Inserted if field "Reason for no classification" is populated AND "Status" <> "67/548/EEC annex 1".]

**Justification for classification or non-classification:** <Justification for classification or non-classification>

## 7. ENVIRONMENTAL HAZARD ASSESSMENT

### 7.1. Aquatic compartment (including sediment)

#### 7.1.1. Toxicity test results

<Discussion> [IUCLID source: Endpoint summary 6.1 Aquatic toxicity.]

##### 7.1.1.1. Fish

###### 7.1.1.1.1. Short-term toxicity to fish

[IUCLID source: section 6.1.1 Short-term toxicity to fish.]

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture according to the following order of priority: "LC50-96 h / 4 d", "LC50-72 h / 3 d", "LC50-48 h / 2 d", "LC50-24 h / 1 d", "LC50", or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "LC50"; (2) "LC0"; (3) "LC100"; (4) any other; (II.) Field "Duration+Unit" (1) "96 h"; (2) "4 d"; (3) "72 h"; (4) "3 d"; (5) "48 h"; (6) "2 d"; (7) "24 h"; (8) "1 d"; (9) any other.]

The results are summarised in the following table:

**Table 93. Overview of short-term effects on fish**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>)	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** [IUCLID source: Endpoint summary 6.1.1 Short-term toxicity to fish.]

<Discussion>

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

<Short description of key information>

#### Value used for CSA:

LC50 for freshwater fish: <Key value for CSA> <Unit>

LC50 for marine water fish: <Key value for CSA> <Unit>

#### 7.1.1.1.2. Long-term toxicity to fish

[IUCLID source: section 6.1.2 Long-term toxicity to fish.

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture according to the following order of priority: "NOEC", "LOEC", "EC10", "IC10" or "LC10" or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10"; (4) "LC10"; (5) "IC10"; (6) any other.]

The results are summarised in the following table:

**Table 94. Overview of long-term effects on fish**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Life stage / endpoint studied> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

#### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

#### Testing proposal

**Information requirement:** Long-term toxicity testing on fish (<Test type>) [Depending on the phrase selected in this IUCLID field, one of the following test types is specified: "early-life stage: reproduction, (sub)lethal effects" (or "life cycle: reproduction, (sub)lethal effects"), "embryo and sac-fry stage: (sub)lethal effects", "juvenile fish: growth".]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

#### **Details on method intended:**

<Principles of method if other than guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type> [Second "Test type" field for specifying "static", "semi-static" or "flow-through".]

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Test conditions: <Details on test conditions>

**Discussion** [IUCLID source: Endpoint summary 6.1.2 Long-term toxicity to fish.]

<Discussion>

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

EC10/LC10 or NOEC for freshwater fish: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for marine water fish: <Key value for CSA> <Unit>

### 7.1.1.2. Aquatic invertebrates

#### 7.1.1.2.1. Short-term toxicity to aquatic invertebrates

[IUCLID source: section 6.1.3 Short-term toxicity to aquatic invertebrates.

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture according to the following order of priority: "EC/IC/LC50-24 h / 1 d", "EC/IC/LC50-48 h / 2 d", "EC/IC/LC50", any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "EC50" or "IC50" or "LC50"; (2) "EC0" or "IC0" or "LC0"; (3) "EC100" or "LC100"; (4) any other; (II.) Field "Duration+Unit" = (1) "24 h"; (2) "1 d"; (3) "48 h"; (4) "2 d"; (5) any other.]

The results are summarised in the following table:

**Table 95. Overview of short-term effects on aquatic invertebrates**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured> based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** [IUCLID source: Endpoint summary 6.1.3 Short-term toxicity to aquatic invertebrates.]

<Discussion>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

EC50/LC50 for freshwater invertebrates: <Key value for CSA> <Unit>

EC50/LC50 for marine invertebrates: <Key value for CSA> <Unit>

**7.1.1.2.2. Long-term toxicity to aquatic invertebrates**

[IUCSID source: section 6.1.4 Long-term toxicity to aquatic invertebrates.

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10" or "LC10" or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10"; (4) "LC10"; (5) "IC10"; (6) any other.]

The results are summarised in the following table:

**Table 96. Overview of long-term effects on aquatic invertebrates**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

**Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Testing proposal**

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Test conditions: <Details on test conditions>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Discussion** [IUCLID source: Endpoint summary 6.1.4 Long-term toxicity to aquatic invertebrates.]

<Discussion>

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

EC10/LC10 or NOEC for freshwater invertebrates: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for marine invertebrates: <Key value for CSA> <Unit>

### 7.1.1.3. Algae and aquatic plants

[IUCLID source: sections 6.1.5 Toxicity to aquatic algae and cyanobacteria / 6.1.6 Toxicity to aquatic plants other than algae.]

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "EC20", "IC20", "EC50", or "IC50", or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "EC50" or "IC50"; (2) "NOEC"; (3) "LOEC"; (4) "EC10" or "IC10", (5) "EC20" or "IC20"; (6) "EC0" or "IC0"; (7) "EC100" or "IC100"; (8) any other; (II.) Field "Duration+Unit" (1) "96 h"; (2) "4 d"; (3) "72 h"; (4) "3 d"; (5) "48 h"; (6) "2 d"; (7) "24 h"; (8) "1 d"; (9) any other.]

The results are summarised in the following table:

**Table 97. Overview of effects on algae and aquatic plants**

Method	Results	Remarks	Reference
[IUCLID source: section 6.1.5 Toxicity to aquatic algae and cyanobacteria.]			
<Test organisms (species)> (algae) <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>
[IUCLID source: section 6.1.6 Toxicity to aquatic plants other than algae.]			
<Test organisms (species)> (aquatic plants) <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

---

**Information requirement:** Growth inhibition study with algae / cyanobacteria / Growth inhibition study with aquatic plants other than algae *[If record in section 6.1.5 / 6.1.6, respectively.]*

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **Discussion**

**Effects on algae / cyanobacteria** *[IUCLID source: Endpoint summary 6.1.5 Toxicity to aquatic algae and cyanobacteria.]*

<Discussion>

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

<Short description of key information>

#### **Value used for CSA:**

EC50/LC50 for freshwater algae: <Key value for CSA> <Unit>

EC50/LC50 for marine water algae: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for freshwater algae: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for marine water algae: <Key value for CSA> <Unit>

**Effects on aquatic plants other than algae** *[IUCLID source: Endpoint summary 6.1.6 Toxicity to aquatic plants other than algae.]*

<Discussion>

The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

<Short description of key information>

#### **Value used for CSA:**

EC50/LC50 for freshwater plants: <Key value for CSA> <Unit>

EC50/LC50 for marine water plants: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for freshwater plants: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for marine water plants: <Key value for CSA> <Unit>

#### **7.1.1.4. Sediment organisms**

*[IUCLID source: section 6.2 Sediment toxicity.]*

*Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".*

*Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "LC10", "EC50", "LC50", "LD50" or any other if none of these endpoints applies.*

*Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) "EC0" or "LC0" or "LD0"; (6) any other.]*

The results are summarised in the following table:

**Table 98. Overview of effects on sediment organisms**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test duration type> (<Study type>) <Test type> Sediment: <Type of sediment> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### Discussion [IUCLID source: Endpoint summary 6.2 Sediment toxicity.]

<Discussion>

The following information is taken into account for sediment toxicity for the derivation of PNEC:

<Short description of key information>

#### **Value used for CSA:**

EC50/LC50 for freshwater sediment: <Key value for CSA> <Unit>

EC50/LC50 for marine water sediment: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for freshwater sediment: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for marine water sediment: <Key value for CSA> <Unit>

#### **7.1.1.5. Other aquatic organisms**

[IUCLID source: section 6.1.8 Toxicity to other aquatic organisms.

Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "LC10" "EC50", "LC50", "LD50" or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) "EC0" or "LC0" or "LD0"; (6) any other.]

The results are summarised in the following table:

**Table 99. Overview of effects on other aquatic organisms**

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity [See description of rules in introductory part.]</b>	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** [IUCLID source: Endpoint summary 6.1.8 Toxicity to other aquatic organisms.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

## 7.1.2. Calculation of Predicted No Effect Concentration (PNEC)

### 7.1.2.1. PNEC water

[IUCLID source: Endpoint summary 6. Ecotoxicological information. If no PNEC is provided, the phrase with the qualitative statement entered in field "PNEC ... type" is inserted.]

**Table 100. PNEC water**

Value	Assessment factor	Remarks/Justification
<PNEC aqua (freshwater) type>: <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC freshwater derivation>
<PNEC aqua (marine waters) type>: <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC marine water derivation>
<PNEC aqua (intermittent releases) type>: <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC intermittent releases derivation>

### 7.1.2.2. PNEC sediment

[IUCLID source: Endpoint summary 6. Ecotoxicological information. If no PNEC is provided, the phrase with

*the qualitative statement entered in field "PNEC ... type" is inserted.]*

**Table 101. PNEC water**

Value	Assessment factor	Remarks/Justification
<PNEC sediment type> <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC sediment derivation>

## 7.2. Terrestrial compartment

### 7.2.1. Toxicity test results

<Discussion> *[IUCLID source: Endpoint summary 6.3 Terrestrial toxicity.]*

#### 7.2.1.1. Toxicity to soil macro-organisms

*[IUCLID source: sections 6.3.1 Toxicity to soil macroorganisms except arthropods / 6.3.2 Toxicity to terrestrial arthropods (For records in section 6.3.2 only, if either "Application method" = "soil" or "Test organisms" is of type "soil-dwelling" or "Animal group" = "x (soil-dwelling ...)").*

*Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".*

*Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "LC10", "LD10"*

*"EC50", "LC50", "LD50" or any other if none of these endpoints applies.*

*Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) any other.]*

The results are summarised in the following table:

**Table 102. Overview of effects on soil macro-organisms**

Method	Results	Remarks	Reference
<i>[IUCLID source: section 6.3.1 Toxicity to soil macroorganisms except arthropods.]</i>			
<Test organisms (species)> (<Animal group>) <Test duration type> (<Study type>) Substrate: <Substrate type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>
<i>[IUCLID source: section 6.3.2 Toxicity to terrestrial arthropods.]</i>			
<Test organisms (species)> (<Animal group>) <Test duration type> (<Study type>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> <i>[See description of rules in introductory part.]</i>	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Data waiving** [Note: Data waivers explicitly indicated for non soil-dwelling organisms are covered by CSR section 7.2.1.4 Toxicity to other terrestrial organisms.)]

**Information requirement:** Toxicity to soil macro-organisms except arthropods / Toxicity to soil arthropods / Toxicity to terrestrial arthropods [If record in section 6.3.1 / 6.3.2 / 6.3.2, but fields "Application method", "Animal group" and "Test organisms" empty, respectively.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **Testing proposal**

**Information requirement:** Short-term toxicity testing on invertebrates / Long-term toxicity testing on invertebrates / Toxicity testing on invertebrates [If record in section 6.3.1 or 6.3.2 with "Test duration type" = "short-term toxicity" / 6.3.1 or 6.3.2 with "Test duration type" = "long-term toxicity" / 6.3.1 or 6.3.2 with "Test duration type" = empty, respectively.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Test organisms (species)> (<Animal group>)

Study type: <Study type>

Test conditions: <Details on test conditions>

**Discussion of effects on soil macro-organisms except arthropods** [IUCLID source: Endpoint summary 6.3.1 Toxicity to soil macroorganisms except arthropods.]

<Discussion>

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

Short-term EC50 or LC50 for soil macro-organisms: <Key value for CSA> <Unit>

Long-term EC10/LC10 or NOEC for soil macro-organisms: <Key value for CSA> <Unit>

**Discussion of effects on soil arthropods** [IUCLID source: Endpoint summary 6.3.2 Toxicity to terrestrial arthropods.]

>>>NOTE (please delete this instruction): Move any information related to other than soil arthropods to the CSR section " 7.2.1.4 Toxicity to other terrestrial organisms" <<< [Insert if "Application method" = "contact", "oral", "spray" or "Test organisms" or "Animal group" <> soil-dwelling species/group]

<Discussion>

The following information is taken into account for effects on soil arthropods for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

Short-term EC50 or LC50 for soil arthropods: <Key value for CSA> <Unit>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

Long-term EC10/LC10 or NOEC for soil arthropods: <Key value for CSA> <Unit>

### 7.2.1.2. Toxicity to terrestrial plants

[IUCLID source: section 6.3.3 Toxicity to terrestrial plants.

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results are summarised in the following table:

**Table 103. Overview of effects on terrestrial plants**

Method	Results	Remarks	Reference
<Test organisms (species)> (<Plant group>) <Test duration type> (<Study type>) <Test type> Substrate: <Substrate type> <Guideline> <Principles of method if other than guideline>	<Species> [Only if effect concentrations for multiple species]; <Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### Testing proposal

**Information requirement:** Short-term toxicity testing on plants / Long-term toxicity testing on plants / <??? specify: Short/Long-term> toxicity testing on plants [If "Test duration type" = "short-term toxicity" / "long-term toxicity" / empty, respectively.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

<Test organisms (species)> (<Plant group>)

Study type: <Study type>

Test conditions: <Details on test conditions>

### Discussion

<Discussion>

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

<Short description of key information>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

### Value used for CSA:

Short-term EC50 or LC50: <Key value for CSA> mg/kg soil dw

Long-term EC10/LC10 or NOEC: <Key value for CSA> mg/kg soil dw

### 7.2.1.3. Toxicity to soil micro-organisms

[IUCLID source: section 6.3.4 Toxicity to soil microorganisms.  
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".  
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "EC10"; (3) "EC25"; (4) "EC50"; (5) "EC100"; (6) any other.]

The results are summarised in the following table:

**Table 104. Overview of effects on soil micro-organisms**

Method	Results	Remarks	Reference
Species/Inoculum: <Test organisms (species)> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### Testing proposal

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

#### **Details on method intended:**

<Principles of method if other than guideline>  
Species/Inoculum: <Test organisms (species)>  
Test conditions: <Details on test conditions>

### Discussion [IUCLID source: Endpoint summary 6.3.4 Toxicity to soil microorganisms.]

<Discussion>

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

<Short description of key information>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

#### Value used for CSA:

Short-term EC50 or LC50 for soil micro-organisms: <Key value for CSA> <Unit>

Long-term EC10/LC10 or NOEC for soil micro-organisms: <Key value for CSA> <Unit>

#### 7.2.1.4. Toxicity to other terrestrial organisms

[IUCLID source: section 6.3.2 Toxicity to terrestrial arthropods, only, if "Application method" <> "soil", "Test organisms" <>type "soil-dwelling", "Animal group" <> "x (soil-dwelling ...)".

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "LC10", "LD10"

"EC50", "LC50", "LD50" or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) any other.]

The results are summarised in the following table:

**Table 105. Overview of effects on terrestrial arthropods other than soil macro-organisms**

Method	Results	Remarks	Reference
<Test organisms (species)> (<Animal group>) <Test duration type> (<Study type>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

**Data waiving** [If "Application method" <> "soil", "Test organisms" <>type "soil-dwelling", "Animal group" <> "x (soil-dwelling ...)".]

**Information requirement:** Toxicity to terrestrial arthropods other than soil macro-organisms

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** [IUCLID source: Endpoint summary 6.3.2 Toxicity to terrestrial arthropods.]

>>>NOTE (please delete this instruction): Move any information related to soil arthropods to the CSR section "7.2.1.1 Toxicity to soil macro-organisms", subheading "Discussion of effects on soil arthropods" <<<

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

## 7.2.2. Calculation of Predicted No Effect Concentration (PNEC soil)

[IUCLID source: Endpoint summary 6. Ecotoxicological information.]

Table 106. PNEC soil

Value	Assessment factor	Remarks/Justification
<PNEC soil type>: <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC soil derivation>

## 7.3. Atmospheric compartment

>>>NOTE (please delete this instruction): Move any information related to this section manually from other sections (e.g. from "Toxicity to terrestrial plants" (if fumigation study) or from "Toxicity to other terrestrial organisms" (e.g. if spray application study with honeybees)).<<< [Insert if any endpoint study record is captured from section 6.3.3 (Tox. to terr. plants) with field "Study type" = "\*field study" or from section 6.3.2 (Tox. to terr. arthropods) with field "Application method" = "spray".]

## 7.4. Microbiological activity in sewage treatment systems

### 7.4.1. Toxicity to aquatic micro-organisms

[IUCLID source: section 6.1.7 Toxicity to microorganisms.]

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".

Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "EC50", "IC50", or any other if none of these endpoints applies.

Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "IC10"; (4) "EC50" or "IC50"; (5) "EC0" or "IC0"; (6) any other.]

The results are summarised in the following table:

Table 107. Overview of effects on micro-organisms

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

### Data waiving

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Discussion** [IUCLID source: Endpoint summary 6.1.7 Toxicity to microorganisms.]

<Discussion>

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

EC50/LC50 for aquatic micro-organisms: <Key value for CSA> <Unit>

EC10/LC10 or NOEC for aquatic micro-organisms: <Key value for CSA> <Unit>

## 7.4.2. PNEC for sewage treatment plant

[IUCLID source: Endpoint summary 6. Ecotoxicological information.]

**Table 108. PNEC sewage treatment plant**

Value	Assessment factor	Remarks/Justification
<PNEC STP type>: <PNEC value> <Unit>	<Assessment factor>	Extrapolation method: <Extrapolation method> <Justification for (no) PNEC STP derivation>

## 7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

### 7.5.1. Toxicity to birds

[IUCLID source: section 6.3.5 Toxicity to birds.]

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results are summarised in the following table:

**Table 109. Overview of effects on birds**

Method	Results	Remarks	Reference
<Test organisms (species)> <Test type> <Dose method> Doses: <Nominal and measured doses / concentrations> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> based on: <Basis for effect> Repellency factors: <Repellency factors (if applicable)>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

**Data waiving**

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

**Information requirement:** Long-term or reproductive toxicity to birds / Toxicity to birds [If "Test type" = "reproduction toxicity" / <> "reproduction toxicity", respectively.]

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

### **Testing proposal**

**Information requirement:** Long-term or reproductive toxicity to birds / Toxicity to birds [If "Test type" = "reproduction toxicity" / <> "reproduction toxicity", respectively.]

**Proposed test guideline:** <Guideline>

**Planned study period:** <Study period>

**Details on method intended:**

<Principles of method if other than guideline>

Species: <Test organisms (species)>

Test type: <Test type> (<Dose method>)

Test conditions: <Details on test conditions>

**Discussion** [IUCLID source: Endpoint summary 6.3.5 Toxicity to birds.]

<Discussion>

The following information is taken into account for effects on birds for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:**

Short-term EC50 or LC50 for birds: <Key value for CSA> <Unit>

Long-term EC10/LC10 or NOEC for birds: <Key value for CSA> <Unit>

## **7.5.2. Toxicity to mammals**

[IUCLID source: section 6.3.6 Toxicity to other above-ground organisms.]

Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "weight of evidence"; (3) "supporting study".]

The results are summarised in the following table:

**Table 110. Overview of effects on mammals**

Method	Results	Remarks	Reference
<Test organisms (species)> <Study type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on (<Nominal/Measured>) based on: <Basis for effect>	<Reliability> <Purpose flag> <Study result type> <b>Test material identity</b> [See description of rules in introductory part.]	<Author> <Year>

EC number:  
<EC number>

<Chemical name>

CAS number:  
<CAS number>

### **Data waiving**

**Reason:** <Data waiving>

**Justification:** <Justification for data waiving>

**Discussion** *[IUCLID source: Endpoint summary 6.3.6 Toxicity to other above-ground organisms.]*

<Discussion>

The following information is taken into account for effects on mammals for the derivation of PNEC:

<Short description of key information>

**Value used for CSA:** Short-term EC50 for mammals: <Key value for CSA> <Unit>

**Value used for CSA:** Long-term EC10/LC10 or NOEC for mammals: <Key value for CSA> <Unit>

### **7.5.3. Calculation of PNEC<sub>oral</sub> (secondary poisoning)**

*[IUCLID source: Endpoint summary 6. Ecotoxicological information.]*

**Table 111. PNEC oral**

<b>Value</b>	<b>Assessment factor</b>	<b>Remarks/Justification</b>
<PNEC oral type>: <PNEC value> <Unit>	<Assessment factor>	<Justification for (n) PNEC oral derivation>

### **7.6. Conclusion on the environmental hazard assessment and on classification and labelling**

#### Environmental classification justification

<Environmental classification justification> *[IUCLID source: Endpoint summary 6. Ecotoxicological information.]*

#### No hazard for the environment

>>>NOTE (please delete this instruction): As appropriate provide the reasoning if it can be concluded that there is no hazard for the environment and that the substance has no potential to cause toxic effects if accumulated via the food chain in higher organisms.<<<< *[Temporary default text.]*

#### General discussion

<Discussion>

## **8. PBT AND VPVB ASSESSMENT**

## **9. EXPOSURE ASSESSMENT**

## **10. RISK CHARACTERISATION**

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# REFERENCES

*[At the end of the CSR a list of all references cited is printed.]*

# European Chemicals Agency

IUCLID 5 Guidance and Support

CSR Tool Plugin for IUCLID 5.3  
User Manual  
April 2011 version 3.0

<http://iuclid.eu>

