[This page should be used as a title page for the CAR or RAR and deleted from the CLH report.]

REGULATION (EU) NO 528/2012 CONCERNING THE MAKING AVAILABLE ON THE MARKET AND USE OF BIOCIDAL PRODUCTS

***Assessment of active substances***

**DRAFT RISK ASSESSMENT REPORT**

**(SUBMITTED BY THE APPLICANT)**

[or]

**[DRAFT/FINAL] COMPETENT AUTHORITY REPORT**

[or]

**[DRAFT/FINAL] RENEWAL AUTHORITY REPORT**

**(SUBMITTED BY THE EVALUATING COMPETENT AUTHORITY)**



**<Active substance name>**

**Product type <PT>**

**(Name of product type)**

**EC Number:**

**CAS Number:**

**Index Number:**

**Applicant:**

**Contact details of evaluating CA:**

**Version number: 2.1 Date:**

*[This page should be used as a title page for the CLH report and deleted from the CAR or RAR.]*

**REGULATION (EC) NO 1272/2008 (CLP REGULATION),**

**ANNEX VI, PART 2**

**Proposal for Harmonised Classification and Labelling for a biocidal active substance**

**CLH REPORT**

**<Chemical name>**

**EC Number:**

**CAS Number:**

**Index Number:**

**Contact details of dossier submitter:**

**Version number: 2.1 Date:**

Note on confidential information

Please be aware that this report is intended to be made publicly available. Therefore it should not contain any confidential information. Such information should be provided in a separate confidential Annex to this report, clearly marked as such.

The eCA should delete all these texts when providing the CAR or RAR.

This template is intended to be used as a template for both the proposal for Harmonised Classification and Labelling (CLH report) and the Competent Authority Report (CAR) or Renewal Authority Report (RAR) applicable for substances submitted under BPR (after 2013). The template aligns the current structure of the CAR or RAR with the information to be included in the CLH report.

**Important instructions for the users of this template**

An Assessment Report shall consist of the following parts: Summary, Part A, Part B, Part C and Part D (Appendices).

* For CAR or RAR, all parts should be included.
* The CLH report consists of
  + Summary
  + Part A
  + Appendix V of Part D (which includes References)
  + Appendix VII of Part D (which includes study summaries). The parts used for CLH should be made non-confidential.

**Additional information to be included in the CLH report**

* It should be noted that for the CLH report, a weight of evidence approach should be used, considering all available relevant data from:
  + REACH registration dossier(s)
  + The Rapporteur Member State assessment report(s) submitted for the EU peer review of active substances used in plant protection products (DAR)
  + Relevant and reliable key data from public sources including other EU assessments
* Data from detailed study summaries needed for an independent and transparent assessment, to be included either
  + in Part A under each endpoint or
  + in Part D Appendix VII (e.g. by extracting from IUCLID for new active substances in BPR, please see the instructions for extracting study summaries from IUCLID in Appendix VII of Part D). In the link below, the [template of Annex I to the CLH report (with explanations)](https://echa.europa.eu/documents/10162/13563/clh_report_template_ai_en.doc/8ab5af56-a04a-44e8-98a7-816aa4e5787c) shows an example on how Appendix VII could be compiled and how each study could be presented individually under its own subchapter including the study reference, detailed study summary and results.
  + The format of the detailed study summary of an individual study is flexible, as long as the summary is clearly reported and under the correct hazard class (either in Part A or in in Part D Appendix VII).

For preparation of a CLH report, a close collaboration between biocides and CLP authorities is recommended.

To enable an independent assessment of the data, it may be necessary to add important/detailed information from robust study summaries or full study reports of key endpoints, such as CMR (e.g. historical control incidences of tumour findings, findings from individual animals if differences are seen between animals in same study and dose group).

For reporting certain data e.g. results from studies, please see further guidance in ECHA Practical Guide 3 How to report robust study summaries <https://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf/1e8302c3-98b7-4a50-aa22-f6f02ca54352>

**Justification for the preparation of a common template**

This common template aims to facilitate the work for the evaluating Competent Authority and the CLH dossier submitter and, by that, save time and resources. It aims also to facilitate the alignment of the two processes which is crucial for the decision on approval under BPR. Having RAC opinions on harmonised Classification and Labelling for biocides adopted in time is in the interest of the biocides active substance approval process.

**Implementation schedule**

The common CAR/RAR-CLH template can be used by the MSCAs from the date of its publication.

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[Table B‑26. Summary of acute toxicity studies performed with the product 196](#_Toc63962055)

[Table B‑27. Summary table of in vitro studies on skin corrosion/irritation 197](#_Toc63962056)

[Table B‑28. Summary table of animal studies on skin corrosion/irritation 197](#_Toc63962057)

[Table B‑29. Summary table of human data on skin irritation 198](#_Toc63962058)

[Table B‑30. Summary table of in vitro studies on serious eye damage and eye irritation 198](#_Toc63962059)

[Table B‑31. Summary table of animal studies on serious eye damage and eye irritation 198](#_Toc63962060)

[Table B‑32. Summary table of human data on serious eye damage and eye irritation 199](#_Toc63962061)

[Table B‑33. Summary table of animal studies on respiratory tract irritation 199](#_Toc63962062)

[Table B‑34. Summary table of human data on respiratory tract irritation 199](#_Toc63962063)

[Table B‑35. Summary table of animal studies on skin sensitisation 201](#_Toc63962064)

[Table B‑36. Summary table of human data on skin sensitisation 201](#_Toc63962065)

[Table B‑37. Summary table of animal data on respiratory sensitisation 202](#_Toc63962066)

[Table B‑38. Summary table of human data on respiratory sensitisation 202](#_Toc63962067)

# ASSESSMENT REPORT

# SUMMARY

# ECA PROPOSAL ON THE APPROVAL OF THE ACTIVE SUBSTANCE UNDER THE BPR

The overall conclusion of the eCA is that the [active substance] in product type [XX] may be  
approved/non approved. The detailed grounds for the overall conclusion are described in the assessment report below.

# PRESENTATION OF THE ACTIVE SUBSTANCE

## IDENTITY OF THE ACTIVE SUBSTANCE

Table 1‑1: Main constituent(s)

|  |  |
| --- | --- |
| Main constituent(s) | |
| ISO name |  |
| IUPAC or EC name |  |
| EC number |  |
| CAS number |  |
| Index number in Annex VI of CLP |  |
| Minimum purity / content |  |
| Structural formula |  |

Table 1‑2: Relevant impurities and additives

|  |  |  |
| --- | --- | --- |
| Relevant impurities and additives | | |
| IUPAC name or chemical name or EC name | **Maximum concentration in % (w/w)** | **Index number in Annex VI of CLP** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

*[If impurities/additives are confidential information it is sufficient to state if they do not contribute to the classification. If they do contribute to the classification, they cannot be claimed confidential under CLH (CLP Art. 38 (c), CLP Annex VI 1.1.1.4 and CLP Annex I 1.1.2.2). Composition of the substance is normally included in the confidential Annex to the CAR/RAR.]*

## INTENDED USES AND EFFECTIVENESS

Table 1‑3: Use of the active substance

|  |  |
| --- | --- |
| Product type |  |
| Intended use pattern(s) |  |
| Users |  |

Table 1‑4: Effectiveness of the active substance

|  |  |
| --- | --- |
| Function |  |
| Organisms to be controlled |  |
| Limitation of efficacy including resistance |  |
| Mode of action |  |

*[The tables above should be duplicated e.g. in a case of several PTs.]*

# PROPOSED HARMONISED CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE ACCORDING TO THE CLP CRITERIA

## PROPOSED HARMONISED CLASSIFICATION AND LABELLING FOR THE ACTIVE

**For substance with an existing entry in Annex VI of CLP**

Table 2‑1: Proposed harmonised classification and labelling of the substance

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Index No** | **Chemical name** | **EC No** | **CAS No** | **Classification** | | **Labelling** | | | **Specific Conc. Limits, M-factors and ATEs** | **Notes** |
| **Hazard Class and Category Code(s)** | **Hazard statement Code(s)** | **Pictogram, Signal Word Code(s)** | **Hazard statement Code(s)** | **Suppl. Hazard statement Code(s)** |
| **Current Annex VI entry** | Existing No | Add what is in Annex VI e.g. name (ISO); IUPAC name | Add what is in Annex VI, i.e. EC No or "-" | Add what is in Annex VI, i.e. CAS No or "-" | Add what is in Annex VI | Add what is in Annex VI | Add what is in Annex VI | Add what is in Annex VI | Add what is in Annex VI or leave empty | Add what is in Annex VI or leave empty | Add what is in Annex VI or leave empty |
| **Dossier submitter’s proposal** | Existing No  or  TBD (in case a new Index No is needed) | E.g. name (ISO); IUPAC name (corrections may apply e.g. by ECHA SID team) | EC No or "-" | CAS No or "-" | Retain  Add  Modify  Remove  (see CLP Annex VI Table 1.1. for correct codes) | Retain  Add  Modify  Remove | Retain  Add  Modify  Remove | Retain  Add  Modify -  Remove | Retain  Add  Modify  Remove  or leave empty | Retain  Add  Modify  Remove  or leave empty  ATE e.g. [route of exposure]: ATE = mg/kg bw or mg/mL (vapour) or (dusts or mists)  SCL(s) e.g. [add classification in question]: C ≥ xx%  M-factor(s) e.g. M=xx | Retain  Add  Modify  Remove  or leave empty |
| **Resulting entry in Annex VI if adopted by RAC and agreed by Commission** | Existing No  or  TBD (in case a new Index No is needed) | E.g. name (ISO); IUPAC name (corrections may apply e.g. by ECHA SID team) | EC No or "-" | CAS No or "-" | Add the resulting Hazard Class and Category Code(s) without Retain, Add, Modify or Remove | Add the resulting Hazard Class and Category Code(s) without Retain, Add, Modify or Remove | Add the resulting Pictogram, Signal Word Code(s) without Retain, Add, Modify or Remove | Add the resulting Hazard state  ment Code(s) without Retain, Add, Modify or Remove | Add the resulting Suppl. Hazard statement Code(s) without Retain, Add, Modify or Remove or leave empty | Add the resulting SCL(s), M-factor(s) and ATE(s) without Retain, Add, Modify or Remove or leave empty  ATE  SCL  M-factors | Add the resulting Notes without Retain, Add, Modify or Remove or leave empty |

**For substance with no current entry in Annex VI of CLP**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Index No** | **Chemical name** | **EC No** | **CAS No** | **Classification** | | **Labelling** | | | **Specific Conc. Limits, M-factors and ATEs** | **Notes** |
| **Hazard Class and Category Code(s)** | **Hazard statement Code(s)** | **Pictogram, Signal Word Code(s)** | **Hazard statement Code(s)** | **Suppl. Hazard statement Code(s)** |
| **Current Annex VI entry** | No current Annex VI entry | | | | | | | | | | |
| **Dossier submitter’s proposal** | TBD | name (ISO); IUPAC name (corrections may apply) | EC No or "-" | CAS No or "-" | Add the proposed Hazard Class and Category Code(s) (see CLP Annex VI Table 1.1. for correct codes) | Add the proposed Hazard statement Code(s) | Add the proposed Pictogram Code(s) & Signal Word code(s) | Add the proposed Hazard Statement Code(s) | Add the proposed Supplemental Hazard Statement. codes or leave empty | Add the proposed SCL(s), M-factor(s) and/or ATE(s) or leave empty  ATE e.g. [route of exposure]: ATE = mg/kg bw or mg/mL (vapour) or (dusts or mists)  SCL(s) e.g. [add classification in question]: C ≥ xx%  M-factor(s) e.g. M=xx | Add the proposed notes or leave empty |
| **Resulting entry in Annex VI if adopted by RAC and agreed by Commission** | TBD | name (ISO); IUPAC name (corrections may apply) | EC No or "-" | CAS No or "-" | Add the proposed Hazard Class and Category Code(s) (see CLP Annex VI Table 1.1. for correct codes) | Add the proposed Hazard statement Code(s) | Add the proposed Pictogram Code(s) & Signal Word code(s) | Add the proposed Hazard Statement Code(s) | Add the proposed Supplemental Hazard Statement. codes or leave empty | Add the proposed SCL(s), M-factor(s) and/or ATE(s) or leave empty  ATE e.g. [route of exposure]: ATE = mg/kg bw or mg/mL (vapour) or (dusts or mists)  SCL(s) e.g. [add classification in question]: C ≥ xx%  M-factor(s) e.g. M=xx | Add the proposed notes or leave empty |

Table 2‑2: Reason for not proposing harmonised classification and labelling and the status under CLH consultation

|  |  |  |
| --- | --- | --- |
| Hazard class | Reason for not proposing classification and labelling | Within the scope of consultation *(please select YES or NO from the drop down list) (*yes/no) |
| Explosives | Choose an item. |  |
| Flammable gases (including chemically unstable gases) | Choose an item. |  |
| Oxidising gases | Choose an item. |  |
| Gases under pressure | Choose an item. |  |
| Flammable liquids | Choose an item. |  |
| Flammable solids | Choose an item. |  |
| Self-reactive substances and mixtures | Choose an item. |  |
| Pyrophoric liquids | Choose an item. |  |
| Pyrophoric solids | Choose an item. |  |
| Self-heating substances and mixtures | Choose an item. |  |
| Substances which in contact with water emit flammable gases | Choose an item. |  |
| Oxidising liquids | Choose an item. |  |
| Oxidising solids | Choose an item. |  |
| Organic peroxides | Choose an item. |  |
| Corrosive to metals | Choose an item. |  |
| Desensitised explosives | Choose an item. |  |
| Acute toxicity via oral route | Choose an item. |  |
| Acute toxicity via dermal route | Choose an item. |  |
| Acute toxicity via inhalation route | Choose an item. |  |
| Skin corrosion/irritation | Choose an item. |  |
| Serious eye damage/eye irritation | Choose an item. |  |
| Respiratory sensitisation | Choose an item. |  |
| Skin sensitisation | Choose an item. |  |
| Germ cell mutagenicity | Choose an item. |  |
| Carcinogenicity | Choose an item. |  |
| Reproductive toxicity | Choose an item. |  |
| Specific target organ toxicity-single exposure | Choose an item. |  |
| Specific target organ toxicity-repeated exposure | Choose an item. |  |
| Aspiration hazard | Choose an item. |  |
| Hazardous to the aquatic environment | Choose an item. |  |
| Hazardous to the ozone layer | Choose an item. |  |

*[Please state if harmonised classification is proposed for a hazard class or select one of the following reasons for not proposing harmonised classification for a hazard class: data lacking;data inconclusive; data conclusive but not sufficient for classification;hazard class not assessed in this dossier;harmonised classification proposed;hazard class not applicable (e.g. if the substance is not in the applicable physical state for the hazard class in question or hazard class needs not to be applied based on chemical structure of the substance ).]*

* + 1. HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

*[Relevant background information to complement the CLH proposal may be included here. It is recommended that it is stated whether the substance was previously discussed and/or agreed by the TC C&L (Dir. 67/548/EEC) and the major issues and outcome of the discussions under the previous legislation. Also other previous discussions and conclusions on classification and labelling may be summarised for information.]*

## PROPOSED CLASSIFICATION AND LABELLING AND PACKAGING FOR THE REPRESENTATIVE PRODUCT(S)

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

Table 2‑3: Proposed Classification and Labelling according to Regulation (EC) No 1272/2008

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Classification | | Labelling | | | | |
| Hazard Class and Category | Hazard statements | Pictograms | Signal word | Hazard statements | Suppl. Hazard statements | Precautionary statements |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Table 2‑4: Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## DATA SOURCES

*[This section is aimed for listing the data sources/bases only. The reference list should be provided in Part D Appendix V. For literature search, please indicate here also the key words used in addition to the data base. For CLH it is expected that e.g. REACH registration dossiers (if available) are taken into account.]*

# SUMMARY OF THE HUMAN HEALTH RISK ASSESSMENT

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report”.”]*

## SUMMARY OF THE ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Table 3‑1: Summary of the assessment of effects on human health

|  |  |
| --- | --- |
| Endpoint | Brief description |
| Toxicokinetics | *[Please include a very short description covering absorption, distribution, metabolism and excretion.]* |
| Acute toxicity | *[Please include a very short description.]* |
| Corrosion and irritation | *[Please include a very short description.]* |
| Sensitisation | *[Please include a very short description.]* |
| Repeated dose toxicity | *[Please include a very short description.]* |
| Genotoxicity | *[Please include a very short description.]* |
| Carcinogenicity | *[Please include a very short description.]* |
| Reproductive toxicity | *[Please include a very short description.]* |
| Neurotoxicity | *[Please include a very short description.]* |
| Immunotoxicity | *[Please include a very short description.]* |
| Disruption of the endocrine system | *[Please include a very short description.]* |
| Other effects | *[Please include a very short description.]* |

## REFERENCE VALUES

Table 3‑2: Reference values

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Study | NOAEL/  LOAEL | Overall assessment factor | Value |
| AELshort-term |  |  |  |  |
| AELmedium-term |  |  |  |  |
| AELlong-term |  |  |  |  |
| ADI |  |  |  |  |
| ARfD |  |  |  |  |

*[Please insert rows for additional reference values if necessary, e.g. for local effects.]*

## RISK CHARACTERISATION

*[Please delete subheadings and tables that are not relevant. Please include also conclusion of local risk characterisation, if performed.]*

Table 3‑3: Summary of exposure scenarios[[1]](#footnote-2)

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario number | Scenario  (e.g. mixing/ loading) | Primary or secondary exposure  Brief description of scenario | Exposed group  (e.g. professionals, non-professionals, bystanders) |
| 1. |  |  |  |
| 2. |  |  |  |

Table 3‑4: Conclusion of risk characterisation for industrial user

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include the results of local risk characterisation if relevant.]*

Table 3‑5: Conclusion of risk characterisation for professional user

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include the results of local risk characterisation if relevant.]*

Table 3‑6: Conclusion of risk characterisation for non-professional user

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include the results of local risk characterisation if relevant.]*

Table 3‑7: Conclusion of risk characterisation for indirect exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

# SUMMARY OF THE ENVIRONMENTAL RISK ASSESSMENT

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

## FATE AND BEHAVIOUR IN THE ENVIRONMENT

*[Please delete subheadings/tables that are not relevant.]*

Table 4‑1: Summary table on compartments exposed and assessed

|  |  |  |
| --- | --- | --- |
| Compartment | Exposed (Y/N) | Assessed (Y/N) |
|  |  |  |
|  |  |  |
|  |  |  |

Table 4‑2: Summary table on relevant metabolites/degradants

|  |  |  |
| --- | --- | --- |
| Metabolite/ degradant/transformation- or reaction product | Compartment | % Active Substance |
|  |  |  |
|  |  |  |
|  |  |  |

Table 4‑3: Summary table on relevant physico-chemical and fate and behaviour parameter of the active substance

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Unit | Remarks |
| Molecular weight |  |  |  |
| Log Octanol/water partition coefficient (Log Kow) |  | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) |  | l/kg |  |
| Henry’s Law Constant (20 °C) |  | Pa/m3/mol |  |
| Biodegradability |  |  |  |
| DT50 for biodegradation in surface water |  | d or hr (at 12ºC) |  |
| DT50 for hydrolysis in surface water |  | d or hr (at 12ºC /pH) |  |
| DT50 for photolysis in surface water |  | d or hr |  |
| DT50 for degradation in soil |  | d or hr (at 12ºC) |  |
| DT50 for degradation in air |  | d or hr |  |
| DT50 for degradation in sediment |  | d or hr |  |
| Bioconcentration, aquatic |  |  |  |
| Bioaccumulation, aquatic |  |  |  |
| Bioconcentration, terrestrial |  |  |  |
| Bioaccumulation, terrestrial |  |  |  |

*[Please insert/delete additional parameters if relevant. Please include a similar table for relevant metabolites and/or degradation products.]*

## EFFECTS ASSESSMENT

Table 4‑4: Summary table on calculated PNEC values

|  |  |
| --- | --- |
| Compartment | PNEC |
|  |  |
|  |  |

*[Please insert relevant environmental compartments. Please include a similar table for relevant metabolites and/or degradation products.]*

## EXPOSURE ASSESSMENT

Table 4‑5: Summary table on calculated PEC values

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | PECSTP  [mg/m3] | PECwater [mg/l] | PECsed [mg/kgwwt] | PECseawater [mg/l] | PECseased [mg/kgwwt] | PECsoil [mg/m3] | PECGW1 [μg/l] | PECair [mg/m3] |
| Scenario 1 |  |  |  |  |  |  |  |  |
| Scenario n |  |  |  |  |  |  |  |  |

*[Please insert/delete additional environmental compartments if relevant. Adapt the number of scenarios as necessary. Please include a similar table for relevant metabolites and/or degradation products.]*

## RISK CHARACTERISATION

Table 4‑6: Summary table on calculated PEC/PNEC values

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECseawater | PEC/PNECseased | PEC/PNECsoil |
| Scenario 1 |  |  |  |  |  |  |
| Scenario n |  |  |  |  |  |  |

*[Please insert/delete additional environmental compartments if relevant. Adapt the number of scenarios as necessary. Please include a similar table for relevant metabolites and/or degradation products.]*

**Conclusion:**

*[Please include a short text summarising the conclusion on the risk assessment.]*

# ASSESSMENT OF EXCLUSION CRITERIA, SUBSTITUTION CRITERIA AND POP

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

Table 5‑1: Assessment of exclusion criteria, substitution criteria and POP

|  |  |
| --- | --- |
| Conclusion on exclusion criteria |  |
| Conclusion on CMR |  |
| Conclusion on ED assessment |  |
| Conclusion on PBT and vP/vB criteria |  |
| Conclusion on substitution criteria |  |
| Conclusion on LRTAP/POP assessment |  |

# Assessment of intrinsic properties and effects of the active substance

## General substance information

### Identity of the Substance

Table A‑1: Summary table on substance identity

|  |  |
| --- | --- |
| Summary table on substance identity | |
| Common name (ISO name, synonyms) |  |
| Chemical name (EC name, CA name, IUPAC name) |  |
| EC number |  |
| CAS number |  |
| other CAS numbers (e.g. deleted, related, preferred, alternate) |  |
| Molecular formula |  |
| Molecular weight or molecular weight range |  |
| Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate) | *[If the substance structure demonstrates stereo-isomerism the ratio of these stereo-isomers should be specified. If the ratio is unknown it should be stated as such. For optical isomers a measure of optical activity (specific rotation) should be specified. Indicate here if this information can be found in confidential Annex of the CAR/RAR.]* |
| Description of the manufacturing process and identity of the source (for UVCB substances only) | *[In the case of UVCB substance a full manufacturing process description should be provided including the identity of the source or starting materials and their ratio. Any relevant process parameters should also be specified. Indicate here if this information can be found in confidential Annex of the CAR/RAR.]* |
| Degree of purity (%)\* | *[The minimum and maximum values should be specified. Indicate here if this information can be found in confidential Annex of the CAR/RAR.]* |

Table A‑2: Structural formula

|  |
| --- |
| Structural formula |
|  |

*[Table below should be deleted from the CLH report.]*

Table A‑3: Origin of the natural active substance or precursor(s) of the active substance

|  |
| --- |
| Origin of the natural active substance or precursor(s) of the active substance |
|  |

*[Table below should be deleted from the CLH report.]*

Table A‑4: Method of manufacture

|  |
| --- |
| Method of manufacture |
|  |

*[Please include here a note if this information will be included in the confidential annex, e.g. “Details of the manufacturing process are reported in the confidential annex of the CAR/RAR.”.]*

### Composition of the substance (reference specifications)

Table A‑5: Main constituent(s)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Constituent (chemical name) | Typical concentration (%(w/w)) | Concentration range (%(w/w)) | Current CLH in Annex VI Table 3 (CLP) | Current self- classification and labelling (CLP) | Remarks / Discussion |
|  |  |  |  |  |  |

Table A‑6: Impurities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Constituent (chemical name) | Typical concentration (%(w/w)) | Concentration range (%(w/w)) | Current CLH in Annex VI Table 3 (CLP) | Current self- classification and labelling (CLP) | Remarks / Discussion |
|  |  |  |  |  | *[Origin of impurity (e.g. manufacturing process, starting material).*  *Does the relevant impurity contribute to the classification and labelling?\**  *If no relevant impurities, add: “NA”.]* |

*[The confidential data on impurities will be specified in the confidential annex of the CAR/RAR. If impurities contribute to the classification they cannot be claimed confidential under CLH.]*

*\*If an impurity contributes to the classification, please contact ECHA classification unit during the CLH intention phase.*

Table A‑7: Additives

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Constituent (chemical name) | Typical concentration (%(w/w)) | Concentration range (%(w/w)) | Current CLH in Annex VI Table 3 (CLP) | Current self- classification and labelling (CLP) | Remarks / Discussion |
|  |  |  |  |  | *[Does the additive contribute to the classification and labelling?\*]* |

*[If additives contribute to classification and labelling, they cannot be claimed confidential under CLH.]*

*\*If an additive contributes to the classification, please contact ECHA classification unit during the CLH intention phase.*

*[Two possible tables, A.8a and A.8b are provided for reporting the composition (eco)tox batches and the proposed specification. Please decide on which table to use depending on the numbers of batches used and the number of impurities present in the a.s. and delete the other. After this, please change the number of the table to A.8]*

Table A‑8: Concentration of constituents (main constituents, impurities, additives) in batches used for (eco)toxicity studies and proposed specification

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Constituents | Relevant impurity (yes/no) | Proposed Specification [% w/w] | Batches used for (eco) toxicity studies [% w/w] | | | |
| Batch No.  Study type  (Reference) | Batch No.  Study type  (Reference) | Batch No.  Study type  (Reference) | Batch No.  Study type  (Reference) |
| Active substance |  |  |  |  |  |  |
| IMPURITY 1 |  |  |  |  |  |  |
| IMPURITY 2 |  |  |  |  |  |  |
| … |  |  |  |  |  |  |
| Specification supported | (yes/no\*) |  |  |  |  |  |

*\*If specification is not supported by a batch used in a study, please highlight the constituent(s) which give concern.*

Table A‑9: Concentration of constituents (main constituents, impurities, additives) in batches used for (eco)toxicity studies and proposed specification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Batches used for (eco) toxicity studies [% w/w] | | | | | |
|  | Active substance | IMPURITY 1 | IMPURITY 2 | **…** | Specification supported |
| Relevant impurity (yes or no) |  |  |  |  | (yes/no\*) |
| Batch Proposed Specification [% w/w] No  Study type (Reference) |  |  |  |  |  |
| Batch No  Study type (Reference) |  |  |  |  |  |
| Batch No  Study type (Reference) |  |  |  |  |  |
| … |  |  |  |  |  |

*\*If specification is not supported by a batch used in a study, please highlight the constituent(s) which give concern.*

*[Add columns to the Batches used for (eco) toxicity studies if needed. Please give details on the test substance used in each study as far as known. The purpose of this table is to summarise the available information and not to generate further requirements for data. In cases where the test substance is different from the substance for which CLH is proposed please provide an explanation of why the test substance may be relevant to the proposal, if not explained elsewhere in the report. Please report here if this information is included in the confidential annex. The various batches used for testing and specifications may have been characterised through different analytical methods. Any uncertainty on the reliability of the information such as analytical methods used should be explained as free text below the table. The table can be re-adjusted depending on the situation, i.e. number of constituents and test substances used].*

### Physical and chemical properties of the active substance

Table A‑10: Physical and chemical properties of the active substance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Property | Result | Test method applied or description in case of deviation | Remarks / Discussion / Justification for waiving | References |
| Aggregate state at 20°C and 101.3 kPA |  |  |  |  |
| Physical state (appearance) at 20°C and 101.3 kPA |  |  |  |  |
| Colour at 20°C and 101.3 kPA |  |  |  |  |
| Odour at 20°C and 101.3 kPA |  |  |  |  |
| Melting / freezing point |  |  |  |  |
| Boiling point at Granulometry |  |  |  |  |
| Vapour pressure |  |  |  |  |
| Henry’s law constant |  |  |  |  |
| Surface tension |  |  |  |  |
| Water solubility at 20 °C |  |  |  |  |
| Partition coefficient (n-octanol/water) and its pH dependency |  |  |  |  |
| Thermal stability and identity of breakdown products |  |  |  |  |
| Reactivity towards container material |  |  |  |  |
| Dissociation constant |  |  |  |  |
| Viscosity |  |  |  |  |
| Solubility in organic solvents, including effect of temperature on solubility |  |  |  |  |
| Stability in organic solvents used in biocidal products and identity of relevant degradation products |  |  |  |  |

### Physical hazards and respective characteristics

Table A‑11: Physical hazards and respective characteristics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard class / characteristics | Guideline and Method | Parameter(s) | Results / Waiver | Reference |
| Explosives |  |  |  |  |
| Flammable gases |  |  |  |  |
| Flammable aerosols |  |  |  |  |
| Oxidising gases |  |  |  |  |
| Gases under pressure |  |  |  |  |
| Flammable liquids |  |  |  |  |
| Flammable solids |  |  |  |  |
| Self-reactive substances and mixtures |  |  |  |  |
| Pyrophoric liquids |  |  |  |  |
| Pyrophoric solids |  |  |  |  |
| Self-heating substances and mixtures |  |  |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  |  |  |
| Oxidising liquids |  |  |  |  |
| Oxidising solids |  |  |  |  |
| Organic peroxides |  |  |  |  |
| Corrosive to metals |  |  |  |  |
| Desensitised explosives |  |  |  |  |
| Auto-ignition temperature (liquids and gases) |  |  |  |  |
| Relative self-ignition temperature for solids |  |  |  |  |
| Dust explosion hazard |  |  |  |  |

### Assessment of physical hazards according to the CLP criteria

*[The summary of physical hazards and respective characteristics can be found in Part A, section 1.3.1.1. Please fill only relevant sections. These sections will be filled only if there is data for the physical hazards, otherwise, please keep the heading and numbering of this section and write below: “Not applicable for CLH report”.”.]*

### Explosives

Table A‑12: Summary table of studies on explosive properties\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

*\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.*

### Short summary and overall relevance of the provided information on explosive properties

*[Please make a short summary of studies on explosive properties and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. explosive properties.]*

### Conclusion on classification and labelling for explosive properties

*[ Please conclude on classification and labelling for explosive properties according to the CLP criteria.]*

### Flammable gases (including chemically unstable gases)

Table A‑13: Summary table of studies on flammable gases (including chemically unstable gases)\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on flammable gases (including chemically unstable gases)

*[Please make a short summary of studies on flammable gases (including chemically unstable gases) and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. flammable gases (including chemically unstable gases).]*

### Conclusion on classification and labelling for flammable gases

*[Please conclude on classification and labelling for flammable gases (including chemically unstable gases) according to the CLP criteria.]*

### Flammable aerosols and aerosols

Table A‑14: Summary table of studies on flammable aerosols and aerosols\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on flammable aerosols and aerosols

*[Please make a short summary of studies on flammable aerosols and aerosols and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. flammable aerosols and aerosols.]*

### Conclusion on classification and labelling for flammable aerosols and aerosols

*[Please conclude on classification and labelling for flammable aerosols and aerosols according to the CLP criteria.]*

### Oxidising gases

Table A‑15: Summary table of studies on oxidising gases\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on oxidising gases

*[Please make a short summary of studies on oxidising gases and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. oxidising gases.]*

### Conclusion on classification and labelling for oxidising gases

*[Please conclude on classification and labelling for oxidising gases according to the CLP criteria.]*

### Gases under pressure

Table A‑16: Summary table of studies on gases under pressure\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on gases under pressure

*[Please make a short summary of studies on oxidising gases and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. gases under pressure.]*

### Conclusion on classification and labelling for gases under pressure

*[Please conclude on classification and labelling for gases under pressure according to the CLP criteria.]*

### Flammable liquids

Table A‑17: Summary table of studies on flammable liquids\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on flammable liquids

*[Please make a short summary of studies on flammable liquids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. flammable liquids.]*

### Conclusion on classification and labelling for flammable liquids

*[Please conclude on classification and labelling for flammable liquids according to the CLP criteria.]*

### Flammable solids

Table A‑18: Summary table of studies on flammable solids\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on flammable solids

*[Please make a short summary of studies on flammable solids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. flammable solids.]*

### Conclusion on classification and labelling for flammable solids

*[Please conclude on classification and labelling for flammable solids according to the CLP criteria.]*

### Self-reactive substances

Table A‑19: Summary table of studies on self-reactivity\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on self-reactive substances

*[Please make a short summary of studies on self-reactive substances and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. self-reactive substances.]*

### Conclusion on classification and labelling for self-reactive substances

*[Please conclude on classification and labelling for self-reactive substances according to the CLP criteria.]*

### Pyrophoric liquids

Table A‑20: Summary table of studies on pyrophoric liquids\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on pyrophoric liquids

*[Please make a short summary of studies on pyrophoric liquids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. pyrophoric liquids.]*

### Conclusion on classification and labelling for pyrophoric liquids

*[Please conclude on classification and labelling for pyrophoric liquids according to the CLP criteria.]*

### Pyrophoric solids

Table A‑21: Summary table of studies on pyrophoric solids\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on pyrophoric solids

*[Please make a short summary of studies on pyrophoric solids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. pyrophoric solids.]*

### Conclusion on classification and labelling for pyrophoric solids

*[Please conclude on classification and labelling for pyrophoric solids according to the CLP criteria.]*

### Self-heating substances

Table A‑22: Summary table of studies on self-heating substances\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on self-heating substances

*[Please make a short summary of studies on self-heating substances and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. self-heating substances.]*

### Conclusion on classification and labelling for self-heating substances

*[Please conclude on classification and labelling for self-heating substances according to the CLP criteria.]*

### Substances which in contact with water emit flammable gases

Table A‑23: Summary table of studies on substances which in contact with water emit flammable gases\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on substances which in contact with water emit flammable gases

*[Please make a short summary of studies on substances which in contact with water emit flammable gases and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. substances which in contact with water emit flammable gases.]*

### Conclusion on classification and labelling for substances which in contact with water emit flammable gases

*[Please conclude on classification and labelling for substances which in contact with water emit flammable gases according to the CLP criteria.]*

### Oxidising liquids

Table A‑24: Summary table of studies on oxidising liquids

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on oxidising liquids

*[Please make a short summary of studies on oxidising liquids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. oxidising liquids.]*

### Conclusion on classification and labelling for oxidising liquids

*[Please conclude on classification and labelling for oxidising liquids according to the CLP criteria.]*

### Oxidising solids

Table A‑25: Summary table of studies on oxidising solids

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on oxidising solids

*[Please make a short summary of studies on oxidising solids and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. oxidising solids.]*

### Conclusion on classification and labelling for oxidising solids

*[Please conclude on classification and labelling for oxidising solids according to the CLP criteria.]*

### Organic peroxides

Table A‑26: Summary table of studies on organic peroxides\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on organic peroxides

*[Please make a short summary of studies on organic peroxides and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. organic peroxides.]*

### Conclusion on classification and labelling for organic peroxides

*[Please conclude on classification and labelling for organic peroxides according to the CLP criteria.]*

### Corrosive to metals

Table A‑27: Summary table of studies on the hazard class corrosive to metals\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on the hazard class corrosive to metals

*[Please make a short summary of studies on the hazard class corrosive to metals and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. corrosive to metals.]*

### Conclusion on classification and labelling for corrosive to metals

*[Please conclude on classification and labelling for corrosive to metals according to the CLP criteria.]*

### Desensitised explosives

Table A‑27: Summary table of studies on the hazard class desensitised explosives\*

|  |  |  |  |
| --- | --- | --- | --- |
| Method | Results | Remarks | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

* + 1. **Short summary and overall relevance of the provided information on the hazard class desensitised explosives**

*[Please make a short summary of studies on the hazard class desensitised explosives and conclude on the relevance of the provided data.]*

* + 1. **Comparison with the CLP criteria**

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. desensitised explosives.]*

* + 1. **Conclusion on classification and labelling for desensitised explosives**

*[Please conclude on classification and labelling for desensitised explosives according to the CLP criteria.]*

### Analytical methods for detection and identification

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

Table A‑28: Analytical methods

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance, metabolite/ degradant etc.) | Compartment | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ), Maximum Residue Limits or other limits | Reference |
|  |  |  |  | **Fortification range / Number of measurements** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

## Effects against target organisms

*[Could be deleted from the CLH report. If deleted, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

Function and field of use envisaged

*[Please include information on function and field of use.]*

### Intended uses

*[Should be deleted from the CLH report. Please keep the heading and numbering of this section and write below: “Not applicable for the CLH report. However, a short description of the use and MoA should be included for the CLH report”.]*

Table A‑29: Summary table of intended uses

|  |  |
| --- | --- |
| Summary table of intended use(s) | |
| Product Type |  |
| Product description |  |
| Target organisms (including development stage) |  |
| Description of use(s) |  |
| Mode of action |  |
| Objects to be protected |  |
| Concentration of product in the in-use formulation/product |  |
| Concentration of active substance in the in-use formulation/product |  |
| Application rate(s) |  |
| Frequency of application |  |
| Season/period for use (where relevant) |  |
| Field of use (indoors/outdoors) |  |
| Category(ies) of user(s) |  |
| Instruction for use |  |

*[Tables should be duplicated if needed e.g. if there are more product types or uses.]*

### Summary on efficacy

### Efficacy

Table A‑30: Experimental data on the efficacy of the active substance against target organism(s)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Function | Field of use envisaged | Test substance | Test organism(s) | Test method | Test system / concentrations applied / exposure time | Test results: effects | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Mode of action

*[Please include any information on the mode of action.]*

### Resistance

*[Please include any information on resistance.]*

### Conclusion on efficacy

*[Please include a brief conclusion.]*

## Assessment of effects on Human Health

*[General note: it may not be necessary to compare the data to the criteria for all hazard categories. Generally it is sufficient to justify why the hazard category above and below is not suitable and why the proposed hazard category is warranted.]*

### Toxicokinetics

Table A‑31: Summary table of toxicokinetic studies\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study,  Guideline, GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided toxicokinetic information

*[Please summarise the toxicokinetic information, the proposed metabolic pathway, and the relevance of the toxicokinetic studies for the classification proposal, if relevant.]*

### Values and conclusions used for the risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value(s) used in the Risk Assessment – Oral absorption | |
| Value(s)\* |  |
| Justification for the selected value(s) |  |

\*Please include the concentration range(s) and type of formulation(s) the values are applicable for, if relevant.

|  |  |
| --- | --- |
| Value(s) used in the Risk Assessment – Dermal absorption | |
| Value(s)\*, \*\* |  |
| Justification for the selected value(s) |  |

\*Please include the concentration range(s) and type of formulation(s) the values are applicable for, if relevant.

\*\*The dermal absorption value is applicable for the active substance and might not be usable in product authorization.

|  |  |
| --- | --- |
| Value(s) used in the Risk Assessment – Inhalatory absorption | |
| Value(s)\* |  |
| Justification for the selected value(s) |  |

\*Please include the concentration range(s) and type of formulation(s) the values are applicable for, if relevant.

|  |  |
| --- | --- |
| Conclusion(s) used in the Risk Assessment – Distribution | |
| Conclusion |  |
| Justification for the conclusion |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Conclusion(s) used in the Risk Assessment – Metabolism | |
| Conclusion |  |
| Justification for the conclusion |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Conclusion(s) used in the Risk Assessment – Elimination | |
| Conclusion |  |
| Justification for the conclusion |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Acute toxicity / STOT SE

### Acute oral toxicity

Table A‑32: Summary table of animal studies on acute oral toxicity\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Type of administration (gavage, in diet, other) | Signs of toxicity (nature, onset, duration, severity, reversibility, include concentrations) | Value  LD50 | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available].*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑33: Summary table of human data on acute oral toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available].*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑34: Summary table of other studies relevant for acute oral toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available].*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on acute oral toxicity

*[Please make a short summary of the acute oral toxicity studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. acute oral toxicity.]*

### Conclusion on classification and labelling for acute oral toxicity

*[Please conclude on acute oral toxicity and the classification and labelling for acute oral toxicity according to the CLP classification criteria. Please also include the relevant ATE value.]*

### Conclusion on acute oral toxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Acute oral toxicity | |
| Value |  |
| Justification for the selected value |  |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Acute dermal toxicity

Table A‑35: Summary table of animal studies on acute dermal toxicity\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Surface area | Signs of toxicity (nature, onset, duration, severity, reversibility, include concentrations) | Value  LD50 | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available].*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑36: Summary table of human data on acute dermal toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data are available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑37: Summary table of other studies relevant for acute dermal toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other studies are available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on acute dermal toxicity

*[Please make a short summary of the acute dermal toxicity studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. acute dermal toxicity.]*

### Conclusion on classification and labelling for acute dermal toxicity

*[Please conclude on the classification and labelling for acute dermal toxicity according to the CLP classification criteria. Please also include relevant ATE value.]*

### Conclusion on acute dermal toxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Acute dermal toxicity | |
| Value |  |
| Justification for the selected value |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Acute inhalation toxicity

Table A‑38: Summary table of animal studies on acute inhalation toxicity\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), form (gas, vapour, dust, mist) and particle size (MMAD)  Actual and nominal concentration, Type of administration (nose only / whole body/ head only) | Signs of toxicity (nature, onset, duration, severity, reversibility, include concentrations) | Value  LC50 | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑39: Summary table of human data on acute inhalation toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑40: Summary table of other studies relevant for acute inhalation toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other studies are available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on acute inhalation toxicity

*[Please make a short summary of the acute inhalation toxicity studies and conclude on the relevance of the provided data and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please consider also whether the data indicates that the mechanism of toxicity is corrosivity.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. acute inhalation toxicity.]*

### Conclusion on classification and labelling for 250 acute inhalation toxicity

*[Please conclude on classification and labelling for acute inhalation toxicity according to the CLP criteria. Please include relevant ATE value.]*

### Conclusion on acute inhalation toxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Acute inhalation toxicity | |
| Value |  |
| Justification for the selected value |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Specific target organ toxicity – single exposure Category 1 and 2 (STOT SE 1 and 2)

Table A‑41: Summary table of animal studies on Specific Target Organ Toxicity STOT SE 1 and 2\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results (including target organ and the effect levels) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑42: Summary table of human data on Specific Target Organ Toxicity STOT SE 1 or 2\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report, Route of exposure,  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑43: Summary table of other studies relevant for Specific Target Organ Toxicity STOT SE 1 and 2\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on STOT SE 1 and 2

*[Please make a short summary of the studies relevant for STOT SE 1 and 2 and conclude on the relevance and uncertainty or controversy of the provided data. Please include here also references to the studies summarised in the sections for acute toxicity and/or other sections in the report, if relevant. Please note that several types of studies/endpoints may contribute to the classification of STOT SE 1 and 2, e.g. data on acute effects from any acute or long term studies. All studies contributing to classification of STOT SE 1 and 2 should be referred here. If applicable, please consider the significance of any deviations from the guideline. Please include a discussion on NOAEL/LOAELs in relation to the guidance values for STOT SE 1 and 2.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class and differentiation in question, i.e. STOT SE 1 and 2.]*

### Conclusion on classification and labelling for STOT SE 1 and 2

*[Please conclude on classification and labelling on STOT SE 1 and 2 according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Specific target organ toxicity – single exposure Category 3 (STOT SE 3)

Table A‑44: Summary table of animal studies on STOT SE 3\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results (including type of effect; respiratory tract irritation or narcotic effects) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑45: Summary table of human data on STOT SE 3\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report, Route of exposure,  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑46: Summary table of other studies relevant for STOT SE 3\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on STOT SE 3

*[Please make a short summary of the STOT SE 3 studies (studies including data on respiratory tract irritation and/or on narcotic effects) and conclude on the relevance and uncertainty or controversy of the provided data. Please consider the potential relevance of information from acute neurotoxicity data, if available in section 3.12. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. STOT SE 3.]*

### Conclusion on classification and labelling for STOT SE 3

*[Please conclude on classification and labelling on STOT SE 3 according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Overall conclusion on acute toxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Acute systemic toxicity | |
| Value |  |
| Justification for the selected value |  |
| Proposed classification | *[Please include the existing classification and/or a proposal if relevant]* |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Value/conclusion used in the Risk Assessment – Acute local effects | |
| Value/conclusion |  |
| Justification for the selected value/conclusion |  |

*[If not relevant, please delete the table.]*

### Skin corrosion and irritation

Table A‑47: Summary table of in vitro studies on skin corrosion/irritation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Vehicle,  Doses | Relevant information about the study | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vitro data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑48: Summary table of animal studies on skin corrosion/irritation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results  Average score for erythema/eschar and oedema (24, 48, 72 h) per animal, observations and time point of onset, reversibility, other adverse local/systemic effects, histopathological findings | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑49: Summary table of human data on skin corrosion/irritation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

### Short summary and overall relevance of the provided information on skin corrosion/irritation

*[Please make a short summary of skin corrosion/irritation studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. skin corrosion/irritation.]*

### Conclusion on classification and labelling for skin corrosion/irritation

*[Please conclude on classification and labelling for skin corrosion/irritation according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Overall conclusion on skin irritation and corrosivity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Skin irritation and corrosivity | |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Proposed classification |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Serious eye damage and Eye irritation

Table A‑50: Summary table of in vitro studies on serious eye damage and eye irritation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Vehicle,  Doses | Relevant information about the study | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vitro data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑51: Summary table of animal studies on serious eye damage and eye irritation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results  Average score for corneal opacity, iritis, conjunctival redness and conjunctival oedema (24, 48, 72 h) per animal, observations and time point of onset, reversibility | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑52: Summary table of human data on serious eye damage and eye irritation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

### Short summary and overall relevance of the provided information on serious eye damage/eye irritation

*[Please make a short summary of serious eye damage/eye irritation studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. serious eye damage/eye irritation.]*

### Conclusion on classification and labelling for serious eye damage/eye irritation

*[Please conclude on classification and labelling for serious eye damage/eye irritation according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Overall conclusion on eye irritation and corrosivity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Eye irritation and corrosivity | |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Proposed classification |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Skin sensitisation

Table A‑53: Summary table of animal studies on skin sensitisation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure (e.g. topical/intradermal, induction/challenge if relevant),  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results (e.g. EC3-value or amount of sensitised animals at induction dose) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑54: Summary table of human data on skin sensitisation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study (e.g. description of the test subjects (general population/selected/unselected dermatitis patients/workers), exposure data (induction dose, daily and overall exposure) | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑55: Summary table of other studies relevant for skin sensitisation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Vehicle,  Doses | Relevant information about the study | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please describe here any additional data relevant for this endpoint. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other studies are available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on skin sensitisation

*[Please make a short summary of skin sensitisation studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. skin sensitisation.]*

### Conclusion on classification and labelling for skin sensitisation

*[Please conclude on classification and labelling for skin sensitisation according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Overall conclusion on skin sensitisation related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Skin sensitisation | |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Proposed classification |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Respiratory sensitisation

Table A‑56: Summary table of animal data on respiratory sensitisation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | Results | Remarks | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑57: Summary table of human data on respiratory sensitisation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

Table A‑58: Summary table of other studies relevant for respiratory sensitisation\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Doses, Vehicle | Relevant information about the study | Results | Remarks | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on respiratory sensitisation

*[Please make a short summary of respiratory sensitisation studies and conclude on the relevance of the provided data and uncertainty or controversy of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. respiratory sensitisation.]*

### Conclusion on classification and labelling for respiratory sensitisation

*[Please conclude on classification and labelling for respiratory sensitisation according to the CLP criteria. Consider also a potential need of setting a specific concentration limit.]*

### Overall conclusion on respiratory sensitisation related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Respiratory sensitisation | |
| Value/conclusion |  |
| Justification for the value/conclusion |  |
| Proposed classification |  |

*[If not relevant, please delete the table.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Repeated dose toxicity/STOT RE

### Short term repeated dose toxicity

### Short-term oral toxicity

Table A‑59: Summary table of oral short-term animal studies (usually 28-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure (gavage, in diet, other),  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including also target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑60: Summary table of human data on short-term oral toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Short-term oral toxicity | |
| Value/conclusion | [Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.] |
| Justification for the value/conclusion |  |

*[If not relevant, please delete the table.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Short-term dermal toxicity

Table A‑61: Summary table of dermal short-term animal studies (usually 28-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle,  Dose levels,  Surface area,  Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑62: Summary table of human data on short-term dermal toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Short-term dermal toxicity | |
| Value/conclusion | [Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.] |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Short-term inhalation toxicity

Table A‑63: Summary table of inhalation short-term animal studies (usually 28-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Form (gas, vapour, dust, mist) and particle size (MMAD), Actual and nominal concentration, Type of administration (nose only / whole body/ head only), Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑64: Summary table of human data on short-term inhalation toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Short-term inhalation toxicity | |
| Value/conclusion | [Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.] |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Overall conclusion on short-term repeated dose toxicity related risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Short-term repeated dose systemic toxicity | |
| Value |  |
| Justification for the selected value |  |
| Proposed classification | *[Please see the chapter on STOT RE in section A.3.7.4.]* |

|  |  |
| --- | --- |
| Value/conclusion used in the Risk Assessment – Short-term repeated dose local effects | |
| Value/conclusion |  |
| Justification for the selected value/conclusion |  |
| Proposed classification | *[Please see the chapter on STOT RE in section A.3.7.4.]* |

### Sub-chronic repeated dose toxicity

### Sub-chronic oral toxicity

Table A‑65: Summary table of oral sub-chronic animal studies (usually 90-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure (gavage, in diet, other),  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including also target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑66: Summary table of human data on sub-chronic oral toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Sub-chronic oral toxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Sub-chronic dermal toxicity

Table A‑67: Summary table of dermal sub-chronic animal studies (usually 90-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Surface area, Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑68: Summary table of human data on sub-chronic dermal toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Sub-chronic dermal toxicity | |
| Value/conclusion | [*Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Sub-chronic inhalation toxicity

Table A‑69: Summary table of inhalatory sub-chronic animal studies (usually 90-day studies)\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Form (gas, vapour, dust, mist) and particle size (MMAD), Actual and nominal concentration, Type of administration (nose only / whole body/ head only), Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including also target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑70: Summary table of human data on sub-chronic inhalation toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Sub-chronic inhalation toxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Overall conclusion on sub-chronic repeated dose toxicity related risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Sub-chronic repeated dose systemic toxicity | |
| Value |  |
| Justification for the selected value |  |
| Proposed classification | *[Please see the chapter on STOT RE in section 3.7.4.]* |

|  |  |
| --- | --- |
| Value/conclusion used in the Risk Assessment – Sub-chronic repeated dose local effects | |
| Value/conclusion |  |
| Justification for the selected value/conclusion |  |
| Proposed classification | *[Please see the chapter on STOT RE in section 3.7.4]* |

### Long-term repeated dose toxicity

### Long-term oral toxicity

Table A‑71: Summary table of oral long-term animal studies\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure (gavage, in diet, other),  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑72: Summary table of human data on long-term oral toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Long-term oral toxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Long-term dermal toxicity

Table A‑73: Summary table of dermal long-term animal studies\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Surface area, Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑74: Summary table of human data on long-term dermal toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Long-term dermal toxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Long-term inhalation toxicity

Table A‑75: Summary table of inhalation long-term animal studies\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Form (gas, vapour, dust, mist) and particle size (MMAD), Actual and nominal concentration, Type of administration (nose only / whole body/ head only), Duration of exposure | NOAEL,  LOAEL | Results (all dose levels including severity and magnitude of all effects, including target organs) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑76: Summary table of human data on long-term inhalation toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Long-term inhalation toxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Overall conclusion on long-term repeated dose toxicity related risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Long-term repeated dose systemic toxicity | |
| Value |  |
| Justification for the selected value |  |
| Proposed classification | *[Please see the chapter on STOT RE in section 3.7.4]* |

|  |  |
| --- | --- |
| Value/conclusion used in the Risk Assessment – Long-term repeated dose local effects | |
| Value/conclusion |  |
| Justification for the selected value/conclusion |  |
| Proposed classification | *[Please see the chapter on STOT RE in section 3.7.4]* |

### Specific target organ toxicity – repeated exposure (STOT RE)

### Short summary and overall relevance of the provided information on STOT RE

*[Please make a short summary of the STOT RE studies (i.e. studies on RDT, Reproductive toxicity, Neurotoxicity and Immunotoxicity) and conclude on the relevance and uncertainty or controversy of the provided data for STOT RE. Specific toxic effects (e.g. tumours or effects on reproduction) that are specifically addressed in other sections (e.g. carcinogenicity or reproductive toxicity) are not included here. If applicable, please consider the significance of any deviations from the guideline. Please include a discussion on NOAEL/LOAELs in relation to the guidance values for STOT-RE 1 and 2 respectively.]*

Table A‑77: Effects and corresponding guidance values to assist classification for STOT RE

*[Please extrapolate the guidance values given for 90-day repeated-dose studies if studies of greater or lesser duration than 90 days are reported.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study reference | Target organ effect(s) (all significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed) | Effective dose (mg/kg bw/d) | Length of exposure | Guidance value/extrapolated guidance value when extrapolated to the exposure duration other than 90 days | Classification supported by the study (Cat 1, Cat 2, NC) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of significant adverse target organ effects arising from a repeated exposure to the substance. If no adverse target organ effects, please delete the table and include a statement that adverse target organ effects arising from a repeated exposure to the substance.]*

### Comparison with the CLP criteria

*[Please perform a weight of evidence assessment of all the study results relevant for STOT RE and compare the results with the CLP classification criteria for the hazard class in question, i.e. specific target organ toxicity-repeated exposure. ]*

### Conclusion on classification and labelling for STOT RE

*[Please conclude on classification and labelling on STOT RE according to the CLP criteria. Where classification is applicable consider the relevant routes and target organs (state all organs affected, if known and/or state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard). Consider also a potential need of setting a specific concentration limit.]*

### Genotoxicity / Germ cell mutagenicity

### In vitro

Table A‑78: Summary table of in vitro genotoxicity studies\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Guideline, GLP status, Reliability, Key/supportive study | Test substance (including purity), Vehicle, Doses | Relevant information about the study (e.g. organism (e.g. bacteria), cell type, strains) | Results (including cytotoxicity and +/-S9 mix) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vitro data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Genotoxicity in vitro | |
| Conclusion |  |
| Justification for the conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### In vivo

Table A‑79: Summary table of in vivo genotoxicity studies\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, duration of study,  Guideline, GLP status, Reliability, Key/supportive study | Test substance (including purity), Vehicle, Doses | Relevant information about the study (e.g. species and strain, sex, no per group, route, frequency of application, sampling times, duration of exposure) | Main effects, Observations (specify regarding dose and sampling time) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vivo data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑80: Summary table of human data on genotoxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability of the human data should be described in a text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Genotoxicity in vivo | |
| Conclusion |  |
| Justification for the conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Short summary and overall relevance of the provided information on germ cell mutagenicity

*[Please make a short summary of germ cell mutagenicity studies including other data relevant for this hazard class (e.g. information on toxicokinetics is also relevant to asses if somatic mutagens can reach the gonads) and conclude on the relevance and uncertainty or controversy of the provided data. If ambiguous results are presented please discuss why different results are observed in different tests and the basis of the final conclusion on whether the substance is genotoxic or not. If applicable, please consider the significance of any deviations from the guideline.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. germ cell mutagenicity.]*

### Conclusion on classification and labelling for germ cell mutagenicity

*[Please conclude on classification and labelling for germ cell mutagenicity according to the CLP criteria.]*

### Overall conclusion on genotoxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Genotoxicity | |
| Conclusion |  |
| Justification for the conclusion |  |
| Proposed classification | *[Please include the existing classification and/or a proposal if relevant.]* |

### Carcinogenicity

Table A‑81: Summary table of carcinogenicity studies in animals\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Duration of exposure | NOAEL,  LOAEL | Results (Please indicate any results that might suggest carcinogenic effects, as well as other toxic effects, for all dose levels) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑82: Summary table of human carcinogenicity data\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\* Reliability of the human data should be described in a text form.

Table A‑83: Summary table of other relevant studies for carcinogenicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in yellow. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on carcinogenicity

*[Please make a short summary of carcinogenicity studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline.]*

Table A‑84: Compilation of some factors that may be taken into consideration in classification and labelling

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species and strain | Tumour type and background incidence | Multi-site responses | Progression of lesions to malignancy | Reduced tumour latency | Responses in single or both sexes | Confounding effect by e.g. excessive toxicity? | Route of exposure | MoA and relevance to humans (if data available) |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. Information which is too long for the narrow columns can be included as a free text. Some additional important factors that may be taken into consideration include whether responses are observed in single or several species; whether the substance of concern has similar structural similarity to a substance(s) for which there is good evidence of carcinogenicity; whether absorption, distribution, metabolism and excretion of the substance are similar between animals and humans; whether there is evidence of mutagenic activity in vivo.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. carcinogenicity.]*

### Conclusion on classification and labelling for carcinogenicity

*[Please conclude on classification and labelling on carcinogenicity according to the CLP criteria. Consider also a potential need of setting a specific concentration limit. If relevant, please state route of exposure (only if it is conclusively proven that no other routes of exposure cause the hazard).]*

### Overall conclusion on carcinogenicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Carcinogenicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented above and does not have to be included here.]* |
| Justification for the value/conclusion |  |
| Proposed classification | *[Please include the existing classification and/or a proposal if relevant.]* |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Reproductive toxicity

### Sexual function and fertility

*[Please report here only the adverse effects on sexual function and fertility as it is important to differentiate the hazard class reproductive toxicity into adverse effects on sexual function and fertility or on development and effects on or via lactation. Therefore please report the specific effects of one study e.g. a two-generation study under respective sections and tables (i.e. sections A3.10.1, A3.10.2 and A3.10.3). However, some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, substances with these effects shall be classified as reproductive toxicants.]*

Table A‑85: Summary table of animal studies on adverse effects on sexual function and fertility\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Duration of exposure | NOAELs,  LOAELs (e.g. maternal/parental toxicity, effects on sexual function and fertility) | Results (for all dose levels, specify critical effects on sexual function and fertility for parental animals (and offspring if relevant), report e.g. incidences and severity of the effects for all dose levels) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑86: Summary table of human data on adverse effects on sexual function and fertility\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

Table A‑87: Summary table of other relevant studies for sexual function and fertility\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. This includes the effects on the reproductive organs in the repeated dose studies. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on adverse effects on sexual function and fertility

*[Please make a short summary of studies on adverse effects on sexual function and fertility and discuss and conclude on the toxicological relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please include also a conclusion on NOAEL/LOAELs.]*

### Comparison with the CLP criteria

*[Please compare the information regarding sexual function and fertility toxicity with the CLP classification criteria for the hazard class in question, i.e. reproductive toxicity.]*

### Overall conclusion on sexual function and fertility related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Effects on fertility | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented above and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Developmental toxicity

*[Please report here only the adverse effects on development as it is important to differentiate the hazard class reproductive toxicity into adverse effects on sexual function and fertility or on development and effects on or via lactation. Therefore please report the specific effects of one study e.g. a two-generation study under respective sections and tables (i.e. sections A3.10.1, A3.10.2 and A3.10.3). However, some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, substances with these effects shall be classified as reproductive toxicants.]*

Table A‑88: Summary table of animal studies on adverse effects on development\*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels | NOAELs,  LOAELs (e.g. maternal, teratogenicity, embryotoxicity, offspring, parental, reproductive toxicity) | Results, maternal/parental  (e.g. corrected body weight gain, for all dose levels) | Results, developmental (e.g. pup survival, structural abnormalities, altered growth, functional deficiencies, incidences and severity of the effects for all dose levels) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑89: Summary table of human data on adverse effects on development\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

Table A‑90: Summary table of other relevant studies for developmental toxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If data is available, delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on adverse effects on development

*[Please make a short summary of studies on adverse effects on development including possible neuro- and immunodevelopmental studies and discuss and conclude on the toxicological relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please include also a conclusion on NOAEL/LOAELs.]*

### Comparison with the CLP criteria

*[Please compare the information regarding developmental toxicity with the CLP classification criteria for the hazard class in question, i.e. reproductive toxicity.]*

### Overall conclusion on effects on development related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Effects on development | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented above and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Effects on or via lactation

*[Please report here only the effects on or via lactation as it is important to differentiate the hazard class reproductive toxicity into adverse effects on sexual function and fertility or on development and effects on or via lactation. Therefore please report the specific effects of one study e.g. a two-generation study under respective sections and tables (i.e. sections A.3.10.1, A.3.10.2 and A.3.10.3).]*

Table A‑91: Summary table of animal studies on adverse effects on or via lactation\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels, Duration of exposure | NOAELs,  LOAELs | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑92: Summary table of human data on adverse effects on or via lactation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

Table A‑93: Summary table of other relevant studies for adverse effects on or via lactation\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on effects on or via lactation

*[Please make a short summary of studies on effects on or via lactation and discuss and conclude on the toxicological relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please include also a conclusion on NOAEL/LOAELs.]*

### 

### Comparison with the CLP criteria

*[Please compare the information regarding effects on or via lactation with the CLP classification criteria for the hazard class in question, i.e. reproductive toxicity.]*

### Overall conclusion on effects on or via lactation related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Effects on or via lactation | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented above and does not have to be included here.]* |
| Justification for the value/conclusion |  |

### Conclusion on classification and labelling for reproductive toxicity

*[Please conclude on classification and labelling on reproductive toxicity according to the CLP criteria. Consider also a potential need of setting specific concentration limits. Please note that specific concentration limits should be considered separately for adverse effects on sexual function and fertility; adverse effects on development and on adverse effects on or via lactation.]*

### Overall conclusion on reproductive toxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Reproductive toxicity | |
| Value |  |
| Justification for the selected value |  |
| Proposed classification | *[Please include the existing classification and/or a proposal if relevant.]* |

### Aspiration hazard

Table A‑94: Summary table of evidence for aspiration hazard\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

### Short summary and overall relevance of the provided information on aspiration hazard

*[Please make a short summary of the evidence for aspiration hazard and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. aspiration hazard.]*

### Conclusion on classification and labelling for aspiration hazard

*[Please conclude on classification and labelling on aspiration hazard according to the CLP criteria.]*

### Neurotoxicity

*[If no data is available, please delete all the tables and indicate only that no data is available .There is no need to repeat discussions from other sections (e.g. STOT SE/RE or reproductive toxicity). A summary and a cross reference to the relevant section(s) is sufficient.]*

Table A‑95: Summary table of animal studies on neurotoxicity\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of exposure, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels | NOAEL,  LOAEL | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑96: Summary table of human data on neurotoxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity) | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

### Short summary and overall relevance of the provided information on neurotoxicity

*[Please make a short summary of the neurotoxicity studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please include also a conclusion on NOAEL/LOAELs.]*

### Comparison with the CLP criteria

*[There is no need to include comparison with the CLP criteria here. Please fill in the sentence below.]*

The conclusion on the classification and labelling can be found in chapter(s) *[please specify the chapter(s) e.g. STOT SE, STOT RE and/or Reproductive toxicity].*

### Conclusion on neurotoxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Neurotoxicity | |
| Value/conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the value/conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Immunotoxicity

*[If no data is available, please delete all the tables and indicate only that no data is available. There is no need to repeat discussions from other sections (e.g. STOT SE/RE or reproductive toxicity). A summary and a cross reference to the relevant section(s) is sufficient.]*

Table A‑97: Summary table of in vitro immunotoxicity studies\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Vehicle, Doses | Relevant information about the study | NOAEL,  LOAEL | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vitro data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑98: Summary table of animal studies on immunotoxicity\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of exposure, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels | NOAEL,  LOAEL | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑99: Summary table of human data on immunotoxicity\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

### Short summary and overall relevance of the provided information on immunotoxicity

*[Please make a short summary of the immunotoxicity studies and conclude on the relevance and uncertainty or controversy of the provided data. If applicable, please consider the significance of any deviations from the guideline. Please include also a conclusion on NOAEL/LOAELs.]*

### Comparison with the CLP criteria

*[There is no need to include comparison with the CLP criteria here. Please fill in the sentence below.]*

The conclusion on the classification and labelling can be found in chapter(s) *[please specify the chapter(s) e.g. STOT SE, STOT RE and/or Reproductive toxicity].*

### Conclusion on immunotoxicity related to risk assessment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for the CLH report.”.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Immunotoxicity | |
| Conclusion | *[Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Endocrine disruption

*[If no data is available, delete all the tables and indicate that no data is available. Depending on the type of effect observed, the relevance for classification and labelling is discussed in different sections, e.g. STOT RE or reproductive toxicity.]*

Table A‑100: Summary table of in vitro studies on endocrine disruption\*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method,  Guideline,  GLP status,  Reliability,  Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects (ED relevant effects) | Main effects (other effects) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no in vitro data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑101: Summary table of animal data on endocrine disruption\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of exposure, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no animal data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑102: Summary table of human data on endocrine disruption\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

Table A‑103: Summary table of other evidence on endocrine disruption\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of exposure, Route of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Vehicle, Dose levels | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in grren. Please insert/delete rows according to the number of studies. If no data is available, please delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Endocrine disruption | |
| Conclusion | [Please include conclusions on overall NOAEL/LOAEL values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.] |
| Justification for the conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Further Human data

*[Include here only information that is not described elsewhere in sections A.3.1 to A.3.14. If no further data is available, please delete the table and indicate only that no further data is available. This chapter includes additional data required for biocides, e.g. routine surveillance of plant personnel, medical surveillance data & poisoning cases. Endpoint specific human data (e.g. skin sensitisation) should be reported in the specific chapter of the endpoint.]*

Table A‑104: Summary table of further human data\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability\*\*, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no human data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

\*\*Reliability for human data should be described in text form.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Further human data | |
| Conclusion | *[Please include conclusions on overall values to be used in risk assessment. Note that the conclusion on classification and labelling is presented elsewhere and does not have to be included here.]* |
| Justification for the conclusion |  |

### Other data

*[Include here only information that is not described elsewhere in sections A.3.1 to A.3.15, e.g. mechanistic studies if available. If relevant for classification and labelling, this data and its relevance for classification and labelling should be discussed in appropriate sections, e.g. carcinogenicity or reproductive toxicity. If no data is available, please delete the table and indicate only that no further data is available.]*

Table A‑105: Summary table of other data\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/report,  Reliability, Key/supportive study | Test substance (including purity), Vehicle | Relevant information about the study | Main effects, Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If no data is available, delete the table and include a statement that no other data is available.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Other data | |
| Conclusion |  |
| Justification for the conclusion |  |

## Environmental effects assessment

*[In addition to the results on the active substance, please create summary tables to report any experimental or other relevant information available on the degradants/metabolites under the corresponding sections of Environmental effects assessment.]*

### Fate and distribution in the environment

[*For inorganic substances, include sections on information on fate and behaviour in water and soil*]

### Degradation

### Abiotic degradation

**Hydrolysis**

Table A‑106: Summary table- Hydrolysis\*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | pH | Temp. [°C] | Initial TS concentration, C0[mol/l] | Half-life, DT50 [d] | Coefficient of correlation, r2 | Remarks | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Please provide information (as free text or summary Tables) on breakdown products.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Phototransformation in water**

Table A‑107: Summary table- Photolysis in water\*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Initial molar TS concentration | Total recovery of test substance [% of appl. AS] | Photolysis rate constant (kcp) | Direct photolysis sunlight rate constant (kpE) | Reaction quantum yield (φcE) | Half-life (t1/2E) | Remarks | Reference |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| *To be adapted for photo-oxidation in air* | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Please provide information (as free text or summary Tables) on breakdown products.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Usually this endpoints is not used in the risk assessment, only relevant in very specific cases.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Estimated photo-oxidation in air**

Table A‑108: Summary table- Photo-oxidation in air\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Model | Light protection (yes/no) | Estimated daily (24h) OH concentration [OH/cm³] | Overall OH rate constant [cm³/molecule ec] | Half-life [hr] | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Please provide information (as free text or summary Tables) on breakdown products.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Usually this endpoints is not used in the risk assessment, only relevant in very specific cases.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Biotic degradation, initial studies

**Biodegradability (ready/inherent)**

Table A‑109: Summary table - biodegradation studies (ready/inherent)\*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Inoculum | | | Additional substrate | Test sub-stance concentr | Degradation | | Remarks  [positive control] | Reference |
|  |  |  | Type | Concentration | Adaptation |  |  | Incubation period | Degree [%] |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test on inherent or ready biodegradability according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

*\**Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Rate and route of degradation including identification of metabolites and degradation products

### Biological sewage treatment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report].*

**Aerobic biodegradation**

Table A‑110: Summary table - STP aerobic biodegradation\*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Inoculum | | | Additional substrate | Test sub-stance concentr. | Degradation | | Remarks | Reference |
|  |  |  | Type | Concentration | Adaptation |  |  | Incubation period | Degree [%] |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

*\**Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Anaerobic biodegradation**

Table A‑111: Summary table - STP anaerobic biodegradation \*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Inoculum | | | Additional substrate | Test sub-stance concentr. | Degradation | | Remarks | Reference |
|  |  |  | Type | Concentration | Adaptation |  |  | Incubation period | Degree [%] |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

*\**Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**STP simulation test**

Table A‑112: Summary table - STP simulation test \*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Inoculum | | | Additional substrate | Test sub-stance concentr. | Degradation | | Remarks | Reference |
|  |  |  | Type | Concentration | Adaptation |  |  | Incubation period | Degree [%] |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test on STP simulation according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

*\**Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Biodegradation in freshwater

**Aerobic aquatic degradation**

Table A‑113: Summary table - Freshwater aerobic biodegradation \*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Exposure | Test substance concentration | Incubation period | Degradation  (DT50) | Remarks | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| *1Test according to OECD criteria* | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant. This includes e.g. information on the degradation products, whether half-lives refer to degradation or dissipation/ transformation, test temperature, etc.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Water/sediment degradation test**

Table A‑114: Summary table - fresh water/sediment degradation \*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Exposure | Test system | | Test substance concentration | Incubation period | Degradation (DT50) | Remarks | Reference |
|  |  |  | Water | Sediment |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| *1 Test on STP simulation according to OECD criteria* | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant. This includes e.g. information on the degradation products, pH value, test temperature, degradation vs. dissipation, etc.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Biodegradation in seawater

**Seawater degradation study**

Table A‑115: Summary table - Seawater aerobic biodegradation \*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Exposure | Test substance concentration | Incubation period | Degradation  (DT50) | Remarks | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| *1Test according to OECD criteria* | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant. This includes e.g. information on the degradation products, test temperature, etc.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Seawater/sediment degradation study**

Table A‑116: Summary table - seawater/sediment biodegradation \*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Exposure | Test system | | Test substance concentration | Incubation period | Degradation (DT50) | Remarks | Reference |
|  |  |  | Water | Sediment |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| *1 Test on STP simulation according to OECD criteria* | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant. This includes e.g. information on the degradation products, test temperature, etc.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Higher tier degradation studies in water or sediment

*[Since higher tier studies can have a very specific study design, no general template is provided. Please use the table provided under and adapt it according to the respective study design.]*

### Biodegradation during manure storage

*[This section should be deleted from the CLH report.]*

Table A‑117: Summary table - Biodegradation during manure storage \*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Inoculum | | | Additional substrate | Test sub-stance concentr. | Degradation | | Remarks | Reference |
|  |  |  | Type | Concentration | Adaptation |  |  | Incubation period | Degree [%] |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test on STP simulation according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Biotic degradation in soil

### Laboratory soil degradation studies

**Aerobic biodegradation**

Table A‑118: Summary table - Aerobic biodegradation in soil- laboratory study \*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Test parameter | Test system | | | | Test sub-stance concentr. | Incubation period | Degradation | Remarks | Reference |
|  |  |  | Soil origin | Soil type | pH | OC % |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details (e.g. test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Anaerobic biodegradation**

Table A‑119: Summary table - Anaerobic biodegradation in soil- laboratory study \*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Test type1 | Exposure | Test system | | | | Test sub-stance concentr. | Incubation period | Degradation  DT50 | Remarks | Reference |
|  |  |  | Soil origin | Soil type | pH | OC % |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| *1 Test according to OECD criteria* | | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant. This includes e.g. information on the degradation products, test temperature, etc*.*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Higher tier degradation studies in soil

*[Since higher tier degradation studies can have a very specific study design, in the following only a table for field dissipation studies is provided. In case of additional higher tier studies please use this table as basis and adapt it according to the respective study design.]*

**Field dissipation studies (field studies, two soil types)**

Table A‑120: Summary table - Field dissipation \*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Site | Application rate (g AS/ha) | Surface | Soil type | Soil texture | Test duration | Degradation (DT50) | Degradation  (DT90) | Remarks | Reference |
|  |  |  |  | Soil 1 |  |  |  |  |  |  |
|  |  |  |  | Soil 2 |  |  |  |  |  |  |
|  |  |  |  | Soil 3 |  |  |  |  |  |  |
| *1 Test on STP simulation according to OECD criteria* | | | | | | | | | | |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details (for example, test temperature, etc.) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Short summary and overall relevance of the provided information on degradation and conclusion on rapid degradation for classification and labelling purposes

*[The conclusion from all biotic and abiotic degradation studies will briefly be summarised here and the overall conclusion on rapid degradation for classification and labelling purposes will be reported.]*

### Distribution

### Adsorption onto/desorption from soils

*[Currently information on adsorption onto/desorption from soils is not mandatory for classification. Therefore, the table below may be deleted from the CLH report. However, if information on adsorption/desorption is available, it is recommended to include it in order to help interpretation of the other properties of the substance.*

Table A‑121: Summary table - Adsorption/desorption \*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Soil | Adsorbed AS [%] | Ka | KaOC | Kd  KdOC  Ka/Kd | Kf | 1/n | Remarks | Reference |
|  | Soil 1 |  |  |  |  |  |  |  |  |
|  | Soil 2 |  |  |  |  |  |  |  |  |
|  | Soil 3 |  |  |  |  |  |  |  |  |

Ka = Adsorption coefficient

KaOC = Adsorption coefficient based on organic carbon content

Kd = Desorption coefficient

KdOC = Desorption coefficient based on organic carbon content

Ka/ Kd = Adsorption / Desorption distribution coefficient

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

Table A‑122: Summary table - Adsorption/desorption metabolite/ degradant/ transformation- or reaction product \*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Soil | % of AS | Ka | KaOC | Kd  KdOC  Ka/Kd | Kf | “l/n” | Remarks | Reference |
|  | Soil 1 |  |  |  |  |  |  |  |  |
|  | Soil 2 |  |  |  |  |  |  |  |  |
|  | Soil 3 |  |  |  |  |  |  |  |  |

Ka = Adsorption coefficient

KaOC = Adsorption coefficient based on organic carbon content

Kd = Desorption coefficient

KdOC = Desorption coefficient based on organic carbon content

Ka/ Kd = Adsorption / Desorption distribution coefficient

*[If considered beneficial, please highlight the key studies in green. Please insert a table for each metabolite/degradant.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Higher tier soil adsorption studies

*[Since higher tier studies like column leaching studies, lysimeter studies or field leaching studies can have a very specific study design, no general template is provided. Please use the table provided under A.4.1.2.1 and adapt it according to the respective study design.]*

### Volatilisation

*Regarding volatilisation, please see Part A, section 1.3 Physical and chemical properties of the active substance.*

### Bioaccumulation

**Measured aquatic bioconcentration**

Table A‑123: Summary table - Measured aquatic bioconcentration\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Exposure | Log Kow of AS | Initial concentration of AS | Steady state BCF | Uptake rate constant (K1) | Depur. rate constant (K2) | Depur. time (DT50) | Metabolites | Remarks | Reference |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the method, the test organism should be specified.]*

\*Include additional details (e.g. lipid normalisation to the standard 5%) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

**Estimated aquatic bioconcentration**

Table A‑124: Summary table - Estimated aquatic bioconcentration \*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Basis for estimation | Log Kow (measured) | Estimated BCF for fish (freshwater) | Estimated BCF for fish eating bird/predator | Remarks | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the method, the test organism should be specified.]*

\*Include additional details (e.g. lipid normalisation to the standard 5%) below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Measured terrestrial bioconcentration**

*[This section should be deleted from the CLH report.]*

Table A‑125: Summary table - Measured terrestrial bioconcentration \*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Exposure | Log Kow of AS | Initial concentration of AS | Steady state BCF | Uptake rate constant (K1) | Depur. rate constant (K2) | Depur. time (DT50) | Metabolites | Remarks | Reference |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the method, the test organism should be specified.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Estimated terrestrial bioconcentration**

*[This section should be deleted from the CLH report.]*

Table A‑126: Summary table - Estimated terrestrial bioconcentration \*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Basis for estimation | Log Kow (measured) | Estimated BCF for: | | | | Remarks | Reference |
|  |  | **Terrestrial food chain I** | | **Terrestrial food chain I** | |  |  |
|  |  | Soil dwelling species | Predatory bird/vertebrate | Terrestrial plant | Grazing non-target organism |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the method, the test organism should be specified.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

### Short summary and overall relevance of the provided information on bioaccumulation and conclusion on bioaccumulation potential for classification and labelling purposes

*[The conclusion from all bioaccumulation studies will briefly be summarised here and the overall conclusion on bioaccumulation potential for classification and labelling purposes will be reported.]*

### Monitoring data

*[If monitoring data in any environmental compartment are available, please describe them here. Regarding the CLH report, this section is restricted to the aquatic compartment only (being the relevant one for CLH) and it is at the discretion of the dossier submitter whether to include any such information or not. In the absence of any specific guidance on the use of monitoring data for classification and labelling purposes, this section (in most cases) will be deleted from the CLH report]*

### Effects on environmental organisms

### Atmosphere

*[Include text here if relevant. Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”.]*

### Toxicity to sewage treatment plant (STP) microorganisms

**Inhibition of microbial activity (aquatic)**

Table A‑127: Summary table - Inhibition of microbial activity \*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species/  Inoculum | Endpoint | Exposure | | Results | | | Remarks | Reference |
|  |  |  | Design | Duration | NOEC | EC10 | EC50 |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the method, the test organism should be specified.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Aquatic compartment

### Freshwater compartment

**Acute/short-term toxicity (freshwater)**

Table A‑128: Summary table - acute/short-term aquatic toxicity \*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LC/EC50 |  |  |
| Fish | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Invertebrates | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Algae (growth inhibition)1 | | | | | |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Other aquatic plants | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Rem*arks *column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations. Chronic toxicity values (e.g. NOEC/EC10) must be reported in the chronic/long-term aquatic toxicity table.]*

*[1 ErC50 calculated from growth rate is preferred. If not available please include the biomass value (EbC50) or the unspecified ECx value]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

**Description of the available acute toxicity studies**

*[Please include information on the available acute toxicity studies on fish, aquatic invertebrates, algae and other aquatic organisms. Please report additional study details relevant for the evaluation and the necessary conclusions. Sub-headings can be added if necessary.]*

**Acute (short-term) toxicity to fish**

**Acute (short-term) toxicity to aquatic invertebrates**

**Acute (short-term) toxicity to algae or other aquatic plants**

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Chronic/long-term toxicity (freshwater)**

Table A‑129: Summary table - chronic/long-term aquatic toxicity \*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LOEC/NOEC/EC10 (specify the value) |  |  |
| Fish | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Invertebrates | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Algae1 | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Other aquatic plants | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

1 calculated from growth rate, if not available please include the biomass value (NOEbC/EbCx) or the unspecified NOEC/ECx value

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks* *column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

**Description of the available chronic toxicity studies**

*[Please include information on the available chronic toxicity studies on fish, aquatic invertebrates, algae and other aquatic organisms. Please report additional study details relevant for the evaluation and the necessary conclusions. Sub-headings can be added if necessary.]*

**Chronic toxicity to fish**

**Chronic toxicity to aquatic invertebrates**

**Chronic toxicity to algae or other aquatic plants**

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[If necessary, please include a discussion on pooling data (freshwater/seawater) or discussion on SSD here.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Sediment compartment (freshwater)

**Acute/short-term toxicity (freshwater sediment)**

Table A‑130: Summary table - acute/short-term toxicity to sediment dwelling organisms\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | | | Remarks | Reference |
|  |  |  |  | Design | Duration | NOEC | LC/EC10 | LC/EC50 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant, e.g. whether endpoint was derived for the water and/or sediment phase(s).

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Chronic/long-term toxicity (freshwater sediment)**

Table A‑131: Summary table - chronic/long-term toxicity to sediment dwelling organisms\*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LOEC/NOEC/EC10 (specify the value) |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks* *column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant, e.g. whether endpoint was derived for the water and/or sediment phase(s).

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[If necessary, please include a discussion on pooling data (freshwater/seawater) or discussion on SSD here.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Marine compartment

**Acute/short-term toxicity (seawater)**

Table A‑132: Summary table - acute/short-term aquatic toxicity\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | | | Remarks | Reference |
|  |  |  |  | Design | Duration | NOEC | LC/EC10 | LC/EC50 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Chronic/long-term toxicity (seawater)**

Table A‑133: Summary table - chronic aquatic toxicity\*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LOEC/NOEC/EC10 (specify the value) |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks* *column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[If necessary, please include a discussion on pooling data (freshwater/seawater) or discussion on SSD here.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Seawater sediment compartment

**Acute/short-term toxicity (seawater sediment)**

Table A‑134: Summary table - acute/short-term toxicity to sea sediment dwelling organisms\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | | | Remarks | Reference |
|  |  |  |  | Design | Duration | NOEC | LC/EC10 | LC/EC50 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant, e.g. whether endpoint was derived for the water and/or sediment phase(s).

*Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Chronic/long-term toxicity (sea sediment)**

Table A‑135: Summary table - long-term/ chronic toxicity to sea sediment dwelling organisms\*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LOEC/NOEC/EC10 (specify the value) |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. Under the Remarks* *column, it should be indicated e.g. if the results are based on nominal or measured (initial or mean) concentrations, etc.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant, e.g. whether endpoint was derived for the water and/or sediment phase(s).

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[If necessary, please include a discussion on pooling data (freshwater/seawater) or discussion on SSD here.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Higher tier studies on aquatic organisms

*[Since higher-tier studies like mesocosm studies can have a very specific study design, no general template is provided. Please use the table provided under 4.2.3.1 and adapt it according to the respective study design.]*

### Terrestrial compartment

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”.]*

**Toxicity to terrestrial organisms, acute/short-term tests**

Table A‑136: Summary table - acute/short-term terrestrial toxicity\*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Organic matter (mg/Kg dw) | Results | | | Remarks | Reference |
|  |  |  |  | Design | Duration |  | NOEC | LC/EC10 | LC/EC50 |  |  |
| Earthworm/soil-dwelling non-target invertebrates | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Soil microflora | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Non-target plants | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Bees and other (non-target) arthropods | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Toxicity to terrestrial organisms, chronic/long-term tests**

Table A‑137: Summary table - chronic/long-term terrestrial toxicity\*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results | Remarks | Reference |
|  |  |  |  | Design | Duration | LOEC/NOEC/EC10 (specify the value) |  |  |
| Earthworm/soil-dwelling non-target invertebrates reproduction | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Non-target plants | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Bees and other (non-target) arthropods | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Groundwater

*[Please include any tests or monitoring data in groundwater here. Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”].*

### Birds and mammals

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.]*

Table A‑138: Summary table - toxicity to birds and mammals\*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Test material | Exposure | | Results  [mg a.i./kg bw or feed ] | | | Remarks | Reference |
|  |  |  |  | Design | Duration | LD/LC50 | LOEL/LOEC | NOEL/NOEC |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Maybe not relevant if chronic data are available. Please indicate accordingly.]*

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Primary and secondary poisoning

*Unless absolutely necessary and sufficiently justified, this section should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.]*

**Primary poisoning**

Table A‑139: Summary table - Primary poisoning\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Duration | Remarks | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

**Secondary poisoning**

Table A‑140: Summary table - Secondary poisoning\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Guideline, GLP status, Reliability, Key/supportive study | Species | Endpoint/ Type of test | Duration | Remarks | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies.]*

\*Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Value used in Risk Assessment | |
| Value/conclusion |  |
| Justification for the value/ conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

*[Waiving example: substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD: It has a low log Kow (x.xx), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 11 h in the water/sediment test. The low accumulation potential is supported by low BCF and BMF for fish and earthworms determined by EUSES 2.1.2. The bioconcentration factor for fish is x.xx L/kg and a default BMF of 1. The bioconcentration factor for earthworms is x.xx L/kg and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.]*

### Endocrine disruption

*[At the discretion of the dossier submitter and in the absence of relevant classification criteria that consider data on endocrine disrupting properties, this section may be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”. Please note that, if environmental ED studies are to be included in the CLH report, currently only in-vivo, apical, population-relevant effects related to standard classification endpoints such as survival, growth, reproduction, need be included, as this is the established current RAC practice.]*

Table A‑141: Summary table of ecotoxicological data on endocrine disruption\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Duration of exposure,  Guideline,  GLP status,  Reliability,  Key/supportive study | Species,  Strain,  Sex,  No/Group | Test substance (including purity), Dose levels | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[If considered beneficial, please highlight the key studies in green. Please insert/delete rows according to the number of studies. If not relevant delete the table.]*

\* Include additional details below the table and/or a reference to the Appendix VII containing the study summaries, if relevant.

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Conclusion used in Risk Assessment – Endocrine disruption | |
| Conclusion |  |
| Justification for the conclusion |  |

*[Table below should be deleted from the CLH report.]*

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Derivation of PNECs

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”.]*

Table A‑142: Derivation of PNECs

|  |  |  |
| --- | --- | --- |
| Compartment | PNEC | Remarks/Justification |
| Freshwater | PNECfreshwater: xx.x mg/L | Organism: Fish (O. mykiss)  Endpoint: LC50 (96 h) 0.52 mg/l  Assessment factor: 1000  Extrapolation method: assessment factor (alternative: partitioning coefficient)  Justification: Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates, an assessment factor of 1000 is applied. |
|  |  | Organism:  Endpoint:  Assessment factor:  Extrapolation method:  Justification: |
|  |  | Organism:  Endpoint:  Assessment factor:  Extrapolation method:  Justification: |
|  |  | Organism:  Endpoint:  Assessment factor:  Extrapolation method:  Justification: |

*[Include relevant environmental compartments or species for which PNECs have been derived.]*

### Overall summary of acute and chronic aquatic toxicity data and Comparison with the CLP criteria

### Acute aquatic hazard

Table A‑143: Summary of key information on acute/ short-term aquatic toxicity relevant for aquatic acute classification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method | Species | Test material | Results1 | Remarks | Reference |
| Fish | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Invertebrates | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Algae | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Other aquatic plants | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Other | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1 Indicate if the results are based on (initial or mean) measured or on the nominal concentrations and/or any information on degradants/ metabolites.

*[The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose. Please also note that it is intended to only list the study(ies) triggering classification for acute/ short-term aquatic hazard, and possibly the most sensitive study per trophic level, not all available information on acute/ short-term aquatic toxicity.]*

*[Please compare the information regarding acute/ short-term toxicity in aquatic organisms with the CLP classification criteria for acute/ short-term aquatic hazard classification.]*

### Long-term aquatic hazard (including information on bioaccumulation and degradation)

Table A‑144: Summary of key information on chronic/ long-term aquatic toxicity relevant for aquatic chronic classification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method | Species | Test material | Results1 | Remarks | Reference |
| Fish | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Invertebrates | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Algae | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Other aquatic plants | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Other | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1 Indicate if the results are based on (initial or mean) measured or on the nominal concentrations and/or any information on degradants/ metabolites.

*[The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose. Please also note that it is intended to only list the study(ies) triggering classification for chronic/ long-term aquatic hazard, and possibly the most sensitive study per trophic level, not all available information on chronic/ long-term aquatic toxicity.]*

*[Compare with the CLP Regulation criteria to conclude on rapid degradability of the substance].*

*[Compare with the CLP Regulation criteria to conclude on potential or actual bioaccumulation of the substance].*

*[Compare the information regarding Long-term/ chronic toxicity in aquatic organisms with the CLP classification criteria for long-term/ chronic aquatic hazard. If no adequate long-term/ chronic toxicity data are available for all three trophic levels (fish, crustacea, algae/aquatic plants), consider using the surrogate approach (Figure 4.1.1 and Table 4.1.0 in Annex I to CLP)...]*

### Conclusion on classification and labelling for environmental hazards and comparison with the CLP criteria

*[Please provide separate conclusions on classification for acute and long-term aquatic hazards. When a substance is classified as Aquatic Acute 1 and/or Aquatic Chronic 1, (a) multiplying factor(s) (M-factor) has/have to be assigned. Where appropriate, M-factors shall be set for short-term and long-term aquatic hazards separately. This means that there can be two different M-factors (one for acute and one for long-term hazard) for one substance. In cases where chronic data are not available and the surrogate approach is used for defining the long-term aquatic hazard, the resulting M-factor derived for acute aquatic hazard classification is also applied to the long-term aquatic hazard classification.]*

## Assessment of additional hazards

### Hazardous to the ozone layer

Table A‑145: Summary table of data concerning hazardous properties of the substance for the ozone layer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of study/data | Test substance | Relevant information about the study (as applicable) | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]*

### Short summary and overall relevance of the provided information on ozone layer hazard

*[Please make a short summary of the studies for ozone layer hazard and conclude on the relevance of the provided data.]*

### Comparison with the CLP criteria

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. hazardous to the ozone layer.]*

**Conclusion on classification and labelling for hazardous to the ozone layer**

*[Please conclude on classification and labelling on hazardous to the ozone layer according to the CLP criteria.]*

## Additional Labelling

*[If relevant, please justify here the reason for supplemental hazard information in accordance with Annex II of the CLP Regulation.]*

## Assessment of exclusion criteria, substitution criteria and POP

*[Should be deleted from the CLH report. However, please keep the heading and numbering of this section and write below: “Not applicable for CLH report.”.]*

### Exclusion criteria

### Assessment of CMR properties

|  |  |
| --- | --- |
| Criteria (BPR Article 5[1]) | Assessment |
| Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B | Active substance is not classified and does not meet the criteria to be classified as Carc. Cat. 1A or 1B. |
| Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B | Active substance is not classified and does not meet the criteria to be classified as Muta. Cat. 1A or 1B. |
| Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B | Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 1A or 1B. |
| Conclusion on CMR properties: | **The exclusion criteria in BPR Article 5(1)a-c are not met.** |

### Assessment of endocrine disrupting properties

|  |  |
| --- | --- |
| Criteria (BPR Article 5) | Assessment |
| Active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 are considered as having endocrine-disrupting properties that may cause adverse effects in humans and to the environment. | The assessment should be made in accordance with the scientific criteria set out in COMMISSION DELEGATED REGULATION (EU) 2017/2100. |
| Conclusion on ED properties: |  |

### PBT Assessment (following Annex XIII to Regulation (EC) No 1907/2006)

**Assessment of persistence**

**Screening**

*Include a persistence assessment based on the criteria for identification of persistent or very persistent substances based on REACH Annex XIII and summarised in the tables below:*

In this context it is important to note that a substance may consist of more than one constituent or that it may form transformation or degradation products. If the substance contains one or more constituents with PBT/vPvB properties in individual amounts ≥ 0.1 % (w/w) or if transformation/degradation products with the respective properties in individual amounts ≥ 0.1 % are being generated, the substance must be treated like a PBT/vPvB.

**Assessment**

|  |  |
| --- | --- |
| P Criteria | Assessment |
| T1/2 > 60 days in seawater, or |  |
| T1/2 > 40 days in fresh- or estuarine water, or |  |
| T1/2 > 180 days in seawater sediment, or |  |
| T1/2 > 120 days in freshwater- or estuarine sediment, or |  |
| T1/2 <= 120 days in soil. |  |

|  |  |
| --- | --- |
| vP Criteria | Assessment |
| T1/2 > 60 days in sea-, fresh- or estuarine water, or |  |
| T1/2 > 180 days in seawater-, freshwater- or estuarine sediment, or |  |
| T1/2 > 180 days in soil. |  |

|  |  |
| --- | --- |
| Conclusion on P / vP properties: |  |

**Assessment of bioaccumulation**

**Screening**

*[Include assessment of screening information provided in REACH Annex XIII:*

*Octanol-water partitioning coefficient experimentally determined or estimated by (Q)SAR models Other information provided that its suitability and reliability can be reasonably demonstrated.]*

**Assessment**

|  |  |
| --- | --- |
| B Criteria | Assessment |
| BCF > 2000 |  |

|  |  |
| --- | --- |
| vB Criteria | Assessment |
| BCF > 5000 |  |

**Assessment of toxicity**

Screening

*[Include assessment of screening information provided in REACH Annex XIII:*

*Short-term aquatic toxicity in accordance with Section 9.1 of Annex VII and Section 9.1.3 of Annex VIII; Other information provided that its suitability and reliability can be reasonably demonstrated.]*

Assessment

|  |  |
| --- | --- |
| T Criteria | Assessment |
| NOEC/EC10 (long-term) < 0.01 mg/L for freshwater or seawater organisms, or |  |
| substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to the CLP Regulation, or |  |
| there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure  (STOT RE category 1 or 2) according to the CLP Regulation. |  |
| Conclusion on T properties: |  |

**Summary and overall conclusions on PBT or vPvB properties**

Overall conclusion:

Based on the assessment described in the subsections above the submission substance is not a PBT / vPvB substance.

### Substitution criteria

*[Include an assessment if the active substance meets any of the following conditions:]*

|  |  |
| --- | --- |
| Substitution criteria (BPR, Article 10) | Assessment |
| One of the exclusion criteria listed in Article 5(1) is met but AS may be approved in accordance with Article 5(2) |  |
| The criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser are met |  |
| The acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario |  |
| Two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 are met |  |
| There are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures |  |
| The AS contains a significant proportion of non-active isomers or impurities. |  |
| Conclusion on substitution criteria: | **The substitution criteria in BPR Article 10(1)a-f are not met.** |

### Assessment of long-range environmental transportation and impact on environmental compartments

|  |  |
| --- | --- |
|  | Assessment |
| The active substance or a degradation product is a persistent organic pollutant (POP) listed in Annex I of EC 850/2004 |  |
| Assessment of long-range transport potential (LRTAP):  Vapour pressure <1000 Pa and  half-life in air > 2 days or  Monitoring data in remote area showing that the substance is found in remote regions or  Result of multimedia modelling |  |
| The active substance or a degradation product is vP/vB or T? |  |
| Conclusion on LRTAP/POP assessment: |  |

# Exposure assessment and effects of the active substance in the biocidal product(s)

**[Parts B, C and D should be deleted from the CLH report, except Appendix V of Part D which includes References**

## General product information

Table B‑1. Identification of the product

|  |  |
| --- | --- |
| Name(s) of the product | |
| Trade name(s) or proposed Trade name(s) |  |
| Manufacturer’s development code and number of the product |  |
| Formulation type |  |

Table B‑2. Complete qualitative and quantitative composition of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Active substance(s) | | | | | |
| ISO or Trivial name | **IUPAC name or other accepted chemical name** | **EC number** | **CAS number** | **Composition / all constituents (upper and lower concentration limit in % (w/w))** | **Concentration in the product in % (w/w)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*Please include here a note if this information will be included in the confidential annex*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Other components / ingredients of the product | | | | | |
| ISO or Trivial name | **IUPAC name or other accepted chemical name** | **EC number** | **CAS number** | **Concentration in in the product in % (w/w)** | **Function** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*Please include here a note if this information will be included in the confidential annex*

*[Please insert/delete rows accordingly.]*

Table B‑3. Physical, chemical and technical properties

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Property | Result | Test method applied or description in case of deviation | Remarks / Discussion / Justification for waiving | References |
| *Physical state at 20°C and 101.3 kPA* |  |  |  |  |
| *Colour at 20°C and 101.3 kPA* |  |  |  |  |
| *Odour at 20°C and 101.3 kPA* |  |  |  |  |
| *Acidity / alkalinity* |  |  |  |  |
| *Relative density* |  |  |  |  |
| Storage stability, stability and shelf-life | | | | |
| *Accelerated storage* |  |  |  |  |
| *Long term storage at ambient temperature* |  |  |  |  |
| *Low temperature stability (liquids)* |  |  |  |  |
| Effects on content of the active substance | | | | |
| *Light* |  |  |  |  |
| *Temperature and humidity* |  |  |  |  |
| *Reactivity towards container material* |  |  |  |  |
| Technical characteristics | | | | |
| *Wettability* |  |  |  |  |
| *Suspensibility, spontaneity and dispersion stability* |  |  |  |  |
| *Wet sieve analysis and dry sieve test* |  |  |  |  |
| *Emulsifiability, re-emulsifiability and emulsion stability* |  |  |  |  |
| *Disintegration time* |  |  |  |  |
| *Particle size distribution, content of dust / fines, attrition, friability* |  |  |  |  |
| *Persistent foaming* |  |  |  |  |
| *Flowability, pourability, dustability* |  |  |  |  |
| *Burning rate – smoke generators* |  |  |  |  |
| *Burning completeness – smoke generators* |  |  |  |  |
| *Composition of smoke – smoke generators* |  |  |  |  |
| *Spraying pattern - aerosols* |  |  |  |  |
| *Other technical characteristics* |  |  |  |  |
| Physical and chemical compatibility with other products including other biocidal products with which its uses is to be authorised | | | | |
| *Physical compatibility* |  |  |  |  |
| *Chemical compatibility* |  |  |  |  |
| *Degree of dissolution and dilution stability* |  |  |  |  |
| *Surface tension* |  |  |  |  |
| *Viscosity* |  |  |  |  |

Table B‑4. Hazard identification for physical and chemical properties

*[Please include a summary on the hazard identification for physical-chemical properties.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Hazard class / characteristics | Guideline and Method | Purity of the test substance (% (w/w) | Parameter(s) | Results / Waiver | Reference |
| *Explosives* |  |  |  |  |  |
| *Flammable gases* |  |  |  |  |  |
| *Flammable aerosols* |  |  |  |  |  |
| *Oxidising gases* |  |  |  |  |  |
| *Gases under pressure* |  |  |  |  |  |
| *Flammable liquids* |  |  |  |  |  |
| *Flammable solids* |  |  |  |  |  |
| *Self-reactive substances and mixtures* |  |  |  |  |  |
| *Pyrophoric liquids* |  |  |  |  |  |
| *Pyrophoric solids* |  |  |  |  |  |
| *Self-heating substances and mixtures* |  |  |  |  |  |
| *Substances and mixtures which in contact with water emit flammable gases* |  |  |  |  |  |
| *Oxidising liquids* |  |  |  |  |  |
| *Oxidising solids* |  |  |  |  |  |
| *Organic peroxides* |  |  |  |  |  |
| *Corrosive to metals* |  |  |  |  |  |
| *Desensitised explosives* |  |  |  |  |  |
| *Auto-ignition temperature (liquids and gases)* |  |  |  |  |  |
| *Relative self-ignition temperature for solids* |  |  |  |  |  |
| *Dust explosion hazard* |  |  |  |  |  |

Table B‑5. Analytical methods for the analysis of the product as such including the active substance, impurities and residues

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Table B‑6. Analytical methods for monitoring

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

**Table B‑7. Analytical methods for soil**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Table B‑8. Analytical methods for air

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Table B‑9. Analytical methods for water

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Table B‑10. Analytical methods for animal and human body fluids and tissues

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Table B‑11. Analytical methods for monitoring of active substances and residues in food and feeding stuff

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|  |  |  |  |  | **Range** | **Mean** | **RSD** |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

## Efficacy

* + 1. Efficacy

Table B‑12. Experimental data on the efficacy of the biocidal product against target organism(s)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Function | Field of use envisaged | Test substance | Test organism(s) | Test method | Test system / concentrations applied / exposure time | | | Test results: effects | Reference |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

* + 1. Mode of action

*[Please include any information on the mode of action.]*

* + 1. Resistance

*[Please include any information on resistance.]*

* + 1. Conclusion on efficacy

*[Please include a brief conclusion.]*

## Human exposure assessment

* + 1. Identification of **main paths of human exposure towards active substance from its use in biocidal product**

Table B‑13. Summary table: relevant paths of human exposure

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Exposure path | Primary (direct) exposure | | | Secondary (indirect) exposure | | | |
| *Industrial use* | *Professional use* | *Non-professional use* | *Industrial use* | *Professional use* | *General public* | *Via food* |
| *Inhalation* |  |  |  |  |  |  |  |
| *Dermal* |  |  |  |  |  |  |  |
| *Oral* |  |  |  |  |  |  |  |

*[Please indicate the main paths of human exposure by stating “yes”,“no” or “n.a.” (not applicable) for each cell.]*

* + 1. List of scenarios

*[This list should contain all scenarios for industrial, professional, non-professional and secondary exposure, but exclude dietary exposure which is covered in Chapter B.3.3.]*

Table B‑14. Summary table: scenarios

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario number | Scenario  (e.g. mixing/ loading) | Primary or secondary exposure  Description of scenario | Exposed group  (e.g. professionals, non-professionals, bystanders) |
| 1. |  |  |  |
| 2. |  |  |  |

*[Please insert or delete rows for additional scenarios as needed. Include all scenarios in this table and then refer to them by their running number given in column 1. If exposure may take place to one person performing different tasks, please include a separate scenario for each type of (sub)task. If the same people may be exposed in several scenarios, there may be the need to evaluate the combined exposure occurring when performing these tasks.]*

### Industrial exposure

**Scenario [n]**

*[Industrial users use biocides in the course of their job or business and they have received suitable information, instruction and training in their use. Industrial users are involved in manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products.*

*Please include a section for each scenario where primary or secondary industrial exposure is foreseen. If no industrial exposure is foreseen, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario and tasks, exposed worker, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter.

\*Only include the parameters changed with respect to the previous Tier.

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
| Scenario [n] |  |  |  |  |
| Scenario [n] |  |  |  |  |

*[Output tables from exposure assessment tools may be included to complement the table.]*

**Further information and considerations on scenario [n]**

*[Please include relevant information and considerations not covered above, e.g. information relevant for risk characterisation for local effects. If not relevant, delete the title.]*

**Combined scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| Exposure scenario | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
| Scenario [n…\*] |  |  |  |
| Scenario [n…\*] |  |  |  |

\* Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

* + 1. Professional Exposure

**Scenario [n]**

*[Professional users use biocides in the course of their job or business and they have received suitable information, instruction and training in their use. Professional users use end-products outside industry.*

*Please include a section for each scenario where primary or secondary professional exposure is foreseen. If no professional exposure is foreseen, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario and tasks, exposed professional worker, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter

\*Only include the parameters changed with respect to the previous Tier.

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
| Scenario [n] |  |  |  |  |
| Scenario [n] |  |  |  |  |

*[Output tables from exposure assessment tools may be included to complement the table.]*

**Further information and considerations on scenario [n]**

*[Please include relevant information and considerations not covered above, e.g. information relevant for risk characterisation for local effects. If not relevant, delete the title.]*

**Combined scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| Exposure scenario | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
| Scenario [n…\*] |  |  |  |
| Scenario [n…\*] |  |  |  |

\* Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

### Non-Professional Exposure

**Scenario [n]**

*[Please include a section for each scenario where primary or secondary non-professional exposure is foreseen. If no non-professional exposure is foreseen, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario and tasks, exposed non-professional worker, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter

\*Only include the parameters changed with respect to the previous Tier.

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [n] |  |  |  |  |  |
| Scenario [n] |  |  |  |  |  |

*[Output tables from exposure assessment tools may be included to complement the table.]*

**Further information and considerations on scenario [n]**

*[Please include relevant information and considerations not covered above, e.g. information relevant for risk characterisation for local effects. If not relevant, delete the title.]*

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Exposure scenario | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [n…\*] |  |  |  |  |
| Scenario [n…\*] |  |  |  |  |

\* Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

### Secondary exposure of the general public excluding dietary exposure

**Scenario [n]**

*[Please include a section for each scenario where secondary exposure of the general public is foreseen. If no exposure is foreseen, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario, general public exposed, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter

*\*Only include the parameters changed with respect to the previous Tier.*

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [n] |  |  |  |  |  |
| Scenario [n] |  |  |  |  |  |

*[Output tables from exposure assessment tools may be included to complement the table.]*

**Further information and considerations on scenario [n]**

*[Please include relevant information and considerations not covered above, e.g. information relevant for risk characterisation for local effects. If not relevant, delete the title.]*

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Exposure scenario | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [n…\*] |  |  |  |  |
| Scenario [n…\*] |  |  |  |  |

\* Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

### Dietary exposure

*[Please include a section for each scenario where food, drinking water or livestock exposure is foreseen. If no exposure is foreseen, then only indicate this and delete the tables and text.]*

### List of scenarios

Table B‑15. Summary table of main representative dietary exposure scenarios

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario number | Type of use1 | Description of scenario | Subject of exposure2 |
| 1. |  |  |  |
| 2. |  |  |  |

*1: e.g. animal husbandry, food industry, professional use, residential use.   
2:e.g. chicken, milk, beer*

*[Please insert or delete rows for additional exposure scenarios as needed. Include all scenarios in this table and then refer to them by their running number given in column 1. Do not use the same numbers already used in Chapter B.3.2 List of scenarios.]*

### Information of non-biocidal use of the active substance

*[Please include a section for each area of other (non-biocidal) use of the active substance. Please insert or delete rows as needed.]*

Table B‑16. Summary table of other (non-biocidal) uses

|  |  |  |  |
| --- | --- | --- | --- |
|  | Sector of use1 | Intended use | Reference value(s) 2 |
| 1. |  |  |  |
| 2. |  |  |  |

*1: e.g. plant protection products, veterinary use, food or feed additives  
2: e.g. MRLs. Use footnotes for references.*

### Estimating Livestock Exposure to Active Substances used in Biocidal Products

**Scenario [n]**

*[Please include a section for each relevant scenario. If not relevant, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario, general public exposed, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter

*\*Only include the parameters changed with respect to the previous Tier.*

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for estimating livestock exposure for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Internal dose received by the animal and WCCE\* | | | | | | |
| *Indicate the model/calculations/ database used]* | | | | | | |
|  | **Parameters\*\*** | **Inhalation exposure** | **Dermal exposure** | **Oral exposure** | **Total exposure** | **WCCE** |
| Scenario [n] |  |  |  |  |  |  |
| Scenario [n] |  |  |  |  |  |  |

\*Worst case consumer exposure: combined estimate of the internal dose with the standard food basket as provided in “Volume 8, Notice to Applicants and Guideline, Veterinary medicine products, Establishment of a maximum residue limit (MRL) for veterinary medicinal products in foodstuff of animal origin”;   
\*\*describe the parameters used to derive the WCCE. Use footnotes for references and justifications.

**Further information and considerations on scenario [n]**

*[Please include relevant information and considerations not covered above. If not relevant, delete the title.]*

**Conclusion**

*[Please give a brief conclusion on the acceptability of the scenario.]*

### Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

**Scenario [n]**

*[Please include for each intended representative use scenario a description of scenario; assumptions, parameters and data used for exposure estimation, including refinements if applicable; calculations and result.]*

**Conclusion**

*[Please give a brief conclusion on the acceptability of the scenario.]*

### Estimating transfer of biocidal active substances into foods as a result of non-professional use

**Scenario [n]**

*[Please include for each intended use scenario a description of scenario; assumptions, parameters and data used for exposure estimation; calculations and result.]*

**Conclusion**

*[Please give a brief conclusion on the acceptability of the scenario.]*

### Exposure associated with production, formulation and disposal of the biocidal product

**Scenario [n]**

*[Please include a section for each relevant scenario. If not relevant, then only indicate this and delete the tables and text.]*

|  |  |  |  |
| --- | --- | --- | --- |
| Description of Scenario [n] | | | |
| *[Please replace this text by giving detailed information on the scenario, exposed worker, application method, indoor and/or outdoor use; frequency and (route specific) duration of exposure (include also whether it is short-term, mid-term or long-term exposure); concentration of active substance in product; absorption values (or equivalent) and any other variables and assumptions used in the calculations. Indicate the model/tool/software/database used.]* | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source2** |
| Tier 1 |  |  |  |
|  |  |  |
|  |  |  |
| Tier 2\* |  |  |  |
|  |  |  |
|  |  |  |
| Tier 3\* |  |  |  |
|  |  |  |
|  |  |  |
| Reverse reference scenario\* |  |  |  |
|  |  |  |
|  |  |  |

Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications. The generic parameters should be in separate rows. Where footnotes are used, they should also be on separate rows. The current footnotes are only to explain the table and should be deleted when using the template. Indicate justification or reference to the guidance document for the choice of the value for each parameter.

\*Only include the parameters changed with respect to the previous Tier.

*[Add and delete lines as needed. Output tables from exposure assessment tools may also be included to replace or to complement the table.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix II. If not relevant, delete the title.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Summary table: systemic exposure associated with production, formulation, and disposal | | | | | |
| Exposure scenario | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [n] |  |  |  |  |  |
| Scenario [n] |  |  |  |  |  |

*[Output tables from exposure assessment tools may be included to complement the table.]*

**Further information and considerations on scenario [n].**

*[Please include relevant information and considerations not covered above, e.g. information relevant for risk characterisation for local effects. If not relevant, delete the title.]*

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Summary table: combined systemic exposure associated with production, formulation, and disposal | | | | |
| Scenarios combined | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [n…\*] |  |  |  |  |
| Scenarios [n…\*] |  |  |  |  |

\*Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

### Combined residential scenarios

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenarios combined | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenarios [n…\*] |  |  |  |  |
| Scenarios [n…\*] |  |  |  |  |

\*Please include the Tier where relevant

*[Output tables from exposure assessment tools may be included to complement the table.]*

## Environmental exposure assessment

*[If several PTs are considered, please repeat the following chapters per PT accordingly.]*

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Scenario 1: Disinfection of rooms, furniture and objects  Scenario 2: Disinfection of instruments |
| ESD(s) used | Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001 |
| Approach | *[Please indicate per scenario if the approach is tonnage based, average consumption based or, if both are not applicable, describe the approach chosen.]*  Scenario 1: Average consumption  Scenario 2: Average consumption |
| Distribution in the environment | Calculated based on TGD 2003 (alternative: based on measured data) |
| Groundwater simulation | *[Please indicate per scenario if any simulation for leaching to groundwater using a higher tier model like e.g. one of the FOCUS models was performed.]* |
| Confidential Annexes | NO / YES: In the confidential Annex VI to Part B the tonnage based scenarios 2 and 3 are provided |
| Lifecycle steps assessed | Scenario [n]:  Production: Yes/No  Formulation Yes/No  Use: Yes/No  Service life: Yes/No |
| Remarks |  |

**Biocidal product specific data**

Please include here additional product specific data that may influence the fate, distribution or the toxicity of the active substance (e.g. results of leaching tests).

### Emission estimation

**Scenario [n]**

*[Please include a section for each scenario per PT per life cycle step.]*

Please note only the values which have been included as “Set values” in the emission scenario, default values which are under discussion or when it is possible to choose between different defaults values should be stated in the table.

Table B‑17. Input parameters for calculating the local emission

|  |  |  |  |
| --- | --- | --- | --- |
| Input | Value | Unit | Remarks |
| Scenario: Disinfection of rooms, furniture and objects | | | |
| Application rate of biocidal product [alternative: annual tonnage in the EU] |  | l/m² |  |
| Concentration of active substance in the product |  | g/l |  |

*[Please insert/delete rows according to the number of relevant set values or other necessary input parameters depending on the scenario chosen.]*

**Calculations for Scenario [n]**

*[Please include any relevant calculations here or in Appendix [III]. If not relevant, delete the title.]*

Table B‑18. Resulting local emission to relevant environmental compartments

|  |  |  |
| --- | --- | --- |
| Compartment | Local emission (Elocalcompartment) [kg/d] | Remarks |
| Freshwater |  |  |
| Sediment |  |  |
| Seawater |  |  |
| Seawater sediment |  |  |
| STP |  |  |
| Air |  |  |
| Soil |  |  |
| Groundwater |  |  |

*[Please insert/delete additional compartments if relevant.]*

### Fate and distribution in exposed environmental compartments

Table B‑19. Identification of relevant receiving compartments based on the exposure pathway

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | + | - | - |  | + | + | + | + | - |
| Scenario [n] |  |  |  |  |  |  |  |  |  |

*[Please indicate relevant environmental compartments by stating “yes”,“no” or “not relevant” for each cell. Adapt the number of scenarios as necessary.]*

Table B‑20. Input parameters (only set values) for calculating the fate and distribution in the environment

|  |  |  |  |
| --- | --- | --- | --- |
| Input | Value | Unit | Remarks |
| Molecular weight |  | g/mol |  |
| Melting point |  | °C |  |
| Boiling point |  | °C |  |
| Vapour pressure (at X °C) |  | Pa |  |
| Water solubility (at X °C) |  | mg/l |  |
| Log10 Octanol/water partition coefficient |  | --- |  |
| Organic carbon/water partition coefficient (Koc) |  | l/kg |  |
| Henry’s Law Constant (at X °C)  [if measured data available] |  | Pa \* m3/mol |  |
| Biodegradability | Ready biodegradable |  |  |
| Rate constant for STP [if measured data available] |  | h-1 |  |
| DT50 for biodegradation in surface water |  | d or hr (at 12ºC) |  |
| DT50 for hydrolysis in surface water |  | d or hr (at 12ºC /pH) |  |
| DT50 for photolysis in surface water |  | d or hr |  |
| DT50 for degradation in soil |  | d or hr (at 12ºC) |  |
| DT50 for degradation in air |  | d or hr |  |

*[Please insert/delete rows according to the number of relevant input parameters.]*

Table B‑21. Calculated fate and distribution in the STP [if STP is a relevant compartment]

|  |  |  |  |
| --- | --- | --- | --- |
| Compartment | Percentage [%] | | Remarks |
|  | **Scenario 1** | **Scenario [n]** |  |
| Air |  |  |  |
| Water |  |  |  |
| Sludge |  |  |  |
| Degraded in STP |  |  |  |

### Calculated PEC values

Table B‑22. Summary table on calculated PEC values

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | PECSTP  [mg/m3] | PECwater  [mg/l] | PECsed  [mg/kgwwt] | PECsea-water  [mg/l] | PECsea-sed  [mg/kgwwt] | PECsoil  [mg/m3] | PECGW\*  [μg/l] | PECair  [mg/m3] |
| Scenario 1 |  |  |  |  |  |  |  |  |
| Scenario [n] |  |  |  |  |  |  |  |  |

\*If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.

*[Please insert/delete additional environmental compartments if relevant. Adapt the number of scenarios as necessary. Please include a similar table for relevant metabolites and/or degradation products]*

### Primary and Secondary poisoning

**Primary poisoning**

*[If applicable, please describe how the exposure through primary poisoning was assessed and report the outcome]*

**Secondary poisoning**

Table B‑23. Summary table on estimated theoretical exposition (ETE)

|  |  |  |
| --- | --- | --- |
|  | ETE [mg/kg\*d-1] | ETE [mg/kg\*d-1] |
| Scenario 1 |  |  |
| Scenario [n] |  |  |

*[Please insert/delete additional columns according to the number of species for which ETE was calculated. Adapt the number of scenarios as necessary]*Waiving example if not relevant: substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (x.xx), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 11 h in the water/sediment test. The low accumulation potential is supported by low BCF and BMF for fish and earthworms determined by EUSES 2.1.2. The bioconcentration factor for fish is x.xx l/kg and a default BMF of 1. The bioconcentration factor for earthworms is x.xx l/kg and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

## Assessment of effects on Human Health for the product

### Product(s)

*[Please give details of the product(s), the formulation, the in-use concentration(s), and substance(s) of concern, if relevant]*

### Dermal absorption

*[Please only include additional studies not covered in Part A. If a relevant study performed with the product is included in Part A, please only refer to the respective study. If no data is available, delete the tables and indicate only that no data is available.]*

Table B‑24. Summary table of in vitro studies on dermal absorption

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Guideline,  GLP status, Reliability | Test substance, Vehicle,  Doses (incl. content a.s., formulation(s), physical state & wetting, dose(s) per area and concentration(s) of test substance) | Relevant information about the study (incl. skin type, no. of acceptable donors and replicates, duration of exposure and post-exposure observation, washings) | Absorption data for each compartment and final absorption value (incl. mean and S.D. for each compartment and sub-total, absorption at half study duration t0.5) | Remarks (e.g. major deviations, adjustments for recovery & variability, exclusion of replicates, exclusion of stratum corneum content, etc.) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table B‑25. Summary table of animal studies on dermal absorption

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Method, Duration of study,  Guideline,  GLP status, Reliability | Species, Strain, Sex, No/group | Concentration of test substance/Label Duration of exposure, Vehicle (incl. test formulation, dose(s) per area, duration of exposure and post-exposure observation, washings) | Signs of toxicity | Absorption data for each compartment and final absorption value (incl. mean and S.D. for each compartment and sub-total, absorption at half study duration t0.5) | Remarks (e.g. major deviations, adjustments for recovery & variability, exclusion of animals, exclusion of stratum corneum content, etc.) | Reference |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table.]*

|  |  |
| --- | --- |
| Value(s) used in the Risk Assessment – Dermal absorption | |
| Value(s)\* |  |
| Justification for the selected value(s) |  |

\* Please include the concentration range(s) the values are applicable for, if relevant

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Acute toxicity

*[Please only include additional studies not covered in Part A. If a relevant study performed with the product is included in Part A, please only refer to the respective study. If no data is available, delete the tables and indicate only that no data is available.]*

Table B‑26. Summary of acute toxicity studies performed with the product

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Route | Method Guideline  GLP status, Reliability | Species/Strain/Sex  No/group | Test substance, Vehicle, Dose levels | Signs of toxicity (nature, onset, duration, severity, reversibility) | Value  LD50/LC50 | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

##### Overall conclusion on acute toxicity

|  |  |
| --- | --- |
| Value used in the Risk Assessment – Acute toxicity | |
| Value(s) |  |
| Justification for the selected value(s) |  |
| Classification for the product according to CLP | *[Please include a proposal if relevant]* |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Corrosion and irritation

*[Please only include additional studies not covered in Part A. If a relevant study performed with the product is included in Part A, please only refer to the respective study. If no data is available, delete the tables and indicate only that no data is available.]*

### Skin corrosion and irritation

*[If no data is available, delete all the tables and indicate only that no data is available.]*

Table B‑27. Summary table of in vitro studies on skin corrosion/irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Guideline,  GLP status, Reliability | Test substance, Vehicle, Doses | Relevant information about the study | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table B‑28. Summary table of animal studies on skin corrosion/irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study, Guideline,  GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, Vehicle, Dose levels,  Duration of expo | Results  Average score (24, 48, 72h), observations and time point of onset, reversibility, other adverse local/systemic effects, histopathological findings | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table B‑29. Summary table of human data on skin irritation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/ report, Reliability\* | Test substance, Vehicle | Relevant information about the study | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |

\*Reliability of the human data should be described in a text form.

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

### Serious eye damage and eye irritation

*[If no data is available, delete all the tables and indicate only that no data is available.]*

Table B‑30. Summary table of in vitro studies on serious eye damage and eye irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method, Guideline,  GLP status, Reliability | Test substance, Vehicle, Doses | Relevant information about the study | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table B‑31. Summary table of animal studies on serious eye damage and eye irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study, Guideline,  GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, Vehicle, Dose levels,  Duration of expo | Results  Average score (24, 48, 72h), observations and time point of onset, reversibility | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table B‑32. Summary table of human data on serious eye damage and eye irritation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/ report, Reliability\* | Test substance, Vehicle | Relevant information about the study | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |

\*Reliability of the human data should be described in a text form.

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

### Respiratory tract irritation

*[If no data is available, delete all the tables and indicate only that no data is available.]*

Table B‑33. Summary table of animal studies on respiratory tract irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study, Guideline,  GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, Vehicle, Dose levels,  Duration of exposure | Results  clinical signs, histopathology, reversibility | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies.]*

Table B‑34. Summary table of human data on respiratory tract irritation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/ report, Reliability\* | Test substance, Vehicle | Relevant information about the study | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |

\*Reliability of the human data should be described in a text form.

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
| Conclusion |  |
| Justification for the conclusion |  |

### Overall conclusion on corrosion and irritation

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Corrosion and irritation | |
| Value(s) or Conclusion(s) |  |
| Justification for the selected value/ conclusion |  |
| Classification of the product according to CLP | *[Please include a proposal if relevant]* |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Sensitisation

*[Please only include additional studies not covered in Part A. If a relevant study performed with the product is included in Part A, please only refer to the respective study. If no data is available, delete the tables and indicate only that no data is available.]*

### Skin sensitisation

*[If no data is available, delete all the tables and indicate only that no data is available.]*

Table B‑35. Summary table of animal studies on skin sensitisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study, Route of exposure (topical/intradermal, if relevant) Guideline, GLP status, Reliability | Species, strain, sex, no/ group | Test substance, Vehicle, Dose levels,  duration of exposure | Results (EC value or amount of sensitised animals at induction dose); Evidence for local or systemic toxicity (time course of onset) | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies.]*

Table B‑36. Summary table of human data on skin sensitisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/ report, Reliability\* | Test substance, Vehicle | Relevant information about the study | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |

\*Reliability of the human data should be described in a text form.

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Skin sensitisation | |
| Value/ Conclusion |  |
| Justification for the selected value/ conclusion |  |
| Classification of the product according to CLP | *[Please include a proposal if relevant]* |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Respiratory sensitisation

*[If no data is available, delete all the tables and indicate only that no data is available.]*

Table B‑37. Summary table of animal data on respiratory sensitisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Method,  Duration of study, Guideline, GLP status, Reliability | Species, Strain, Sex, No/ group | Test substance, Vehicle,  Dose levels,  Duration of exposure | Results | Remarks (e.g. major deviations) | Reference |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies.]*

Table B‑38. Summary table of human data on respiratory sensitisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of data/ report, Reliability\* | Test substance, Vehicle | Relevant information about the study | Observations | Reference |
|  |  |  |  |  |
|  |  |  |  |  |

\*Reliability of the human data should be described in a text form.

*[Please insert/delete rows according to the number of studies. If not relevant, delete the table and include a statement that no human data is available.]*

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Respiratory sensitisation | |
| Value/ Conclusion |  |
| Justification for the selected value/ conclusion |  |
| Classification of the product according to CLP | *[Please include a proposal if relevant]* |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Overall conclusion on sensitisation

|  |  |
| --- | --- |
| Conclusion used in the Risk Assessment – Sensitisation | |
| Conclusion(s) |  |
| Justification for the conclusion(s) |  |
| Classification of the product according to CLP | *[Please include a proposal if relevant]* |

|  |  |
| --- | --- |
| Data waiving | |
| Information requirement |  |
| Justification |  |

*[If not relevant, please delete the table.]*

### Other

*[Please include any relevant information and considerations not covered above e.g. synergistic or cumulative effects. If not relevant, delete the title.]*

## Environmental effects assessment for the product

### Atmosphere

*[To be provided accordingly to section A.4.2.1 if there are any compounds in the product that adversively affect the conclusions of the risk assessment for the active substance in the product.]*

Waiving example if not relevant: The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2.1. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

### STP

*[To be provided accordingly to section A.4.2.2 if there are any compounds in the product that adversively affect the conclusions of the risk assessment for the active substance in the product.]*

### Aquatic compartment

*[To be provided accordingly to section A.4.2.3 if there are any compounds in the product that adversively affect the conclusions of the risk assessment for the active substance in the product.]*

### Terrestrial compartment

*[To be provided accordingly to section A.4.2.4 if there are any compounds in the product that adversively affect the conclusions of the risk assessment for the active substance in the product.]*

### Primary and Secondary poisoning

*[To be provided accordingly to section A.4.2.7 if there are any compounds in the product that adversively affect the conclusions of the risk assessment for the active substance in the product.]*

Waiving example if not relevant: substance is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (x.xx), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable and has a short degradation half-life of 11 h in the water/sediment test. The low accumulation potential is supported by low BCF and BMF for fish and earthworms determined by EUSES 2.1.2. The bioconcentration factor for fish is x.xx l/kg and a default BMF of 1. The bioconcentration factor for earthworms is x.xx l/kg and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

# Risk characterisation of the biocidal product(s)

## Risk Characterisation for human health

### Critical endpoints

### Systemic effects

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Acute effects1 | | | | |
| Study | **Route and doses** | **Relevant effects** | **NOAEL/ LOAEL** | **References** |
|  |  |  |  |  |
|  |  |  |  |  |

1This refers to acute effects seen in any of the studies, including also short-term, medium-term and long-term studies.

*[Please insert additional rows if necessary.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Medium-term effects1 | | | | |
| Study | **Route and doses** | **Relevant effects** | **NOAEL/ LOAEL** | **References** |
|  |  |  |  |  |
|  |  |  |  |  |

1This refers to medium-term effects seen in any of the studies, including also long-term studies.

*[Please insert additional rows if necessary.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Long-term effects seen in studies | | | | |
| Study | **Route and doses** | **Relevant effects** | **NOAEL/ LOAEL** | **References** |
|  |  |  |  |  |
|  |  |  |  |  |

*[Please insert additional rows if necessary.]*

Local effects

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Study (reference)  Test substance | Relevant effects  NOAEC/LOAEC | Classification | Hazard category1 |
| Dermal |  |  |  |  |
| Respiratory |  |  |  |  |
| Oral |  |  |  |  |

1According to ECHA guidance Vol III Part B.

*[Please include all reliable studies where local effects were considered relevant. Please insert or delete rows, as appropriate.]*

### Absorption

|  |  |  |  |
| --- | --- | --- | --- |
| Route | Study | Test substance and concentration of a.s. | Value |
| Oral |  |  |  |
| Dermal |  |  |  |
| Inhalation |  |  |  |

*[Please insert additional rows if necessary. Please insert n.a. and use footnote for references and justifications.]*

### Reference values

### Reference values to be used in Risk Characterisation

|  |  |  |
| --- | --- | --- |
| Studies selected for reference value derivation | | |
| Reference value | **Study** | **Rationale for selecting the study** |
| AELshort-term |  |  |
| AELmedium-term |  |  |
| AELlong-term |  |  |
| ARfD |  |  |
| ADI |  |  |
| AEC1 |  |  |

1Please specify route (oral, dermal, inhalation) and duration (short-term, medium-term, long-term).

*[Please insert rows for additional reference values if necessary, e.g. for local effects.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Reference value | NOAEL (LOAEL)  NOAEC/LOAEC | AF | Correction for oral absorption | Value |
| AELshort-term |  |  |  |  |
| AELmedium-term |  |  |  |  |
| AELlong-term |  |  |  |  |
| ARfD |  |  |  |  |
| ADI |  |  |  |  |
| AEC1 |  |  |  |  |

1Please specify route (oral, dermal, inhalation) and duration (short-term, medium-term, long-term).

*[Please insert rows for additional reference values if necessary, e.g. for local effects.]*

### Uncertainties and assessment factors

**Systemic reference values**

|  |  |  |
| --- | --- | --- |
| AELshort-term | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEL to LOAEL extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary.]*

|  |  |  |
| --- | --- | --- |
| AELmedium-term | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEL to LOAEL extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary.]*

|  |  |  |
| --- | --- | --- |
| AELlong-term | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEL to LOAEL extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary.]*

|  |  |  |
| --- | --- | --- |
| ARfD | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEL to LOAEL extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary. Delete the table if no ARfD is derived. If not derived, please justify.]*

|  |  |  |
| --- | --- | --- |
| ADI | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEL to LOAEL extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary. Delete the table if no ADI is proposed. If not derived, please justify.]*

**Local reference values**

*[Please include tables as relevant e.g. for different routes and durations]*

|  |  |  |
| --- | --- | --- |
| AEC | | |
| Uncertainty | **AF** | **Justification** |
| Interspecies variability |  |  |
| Intraspecies variability |  |  |
| Route to route extrapolation |  |  |
| Time duration extrapolation |  |  |
| NOAEC to LOAEC extrapolation |  |  |
| Dose response |  |  |
| Severity of key health effects |  |  |
| Overall AF |  | (n.a.) |

*[Please insert rows for additional uncertainties if necessary. Delete the table if no AEC is derived.]*

### Maximum residue limits or equivalent

|  |  |  |  |
| --- | --- | --- | --- |
| MRLs or other relevant reference values | Reference | Relevant commodities | Value |
|  |  |  |  |
|  |  |  |  |

*[Please insert or delete rows as appropriate.]*

### Specific reference value for groundwater

*[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.*

### Industrial uses

### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each task/scenario where professional exposure is foreseen. If no exposure is foreseen and/or no systemic effect is observed, then only indicate this and delete the table.]*

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenarios combined | Tier/PPE | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each combination of scenarios assessed. If no combined exposure is foreseen, then only indicate this and delete the table.]*

### Local effects

**Risk Characterisation for local effects**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | Risk | | |
| Hazard category | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposures route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[Please include additional rows as necessary[[2]](#footnote-3). If no exposure is foreseen and/or there is no need to consider local effects separately, then only indicate this and delete the table.]*

### Conclusion

*[Please give a brief conclusion on the acceptability of the scenarios.]*

### Professional uses

### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each task/scenario where professional exposure is foreseen. If no exposure is foreseen and/or no systemic effect is observed, then only indicate this and delete the table.]*

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenarios combined | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each combination of scenarios assessed. If no combined exposure is foreseen, then only indicate this and delete the table.]*

### Local effects

**Risk Characterisation for local effects**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | Risk | | |
| Hazard category | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposures route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[Please include additional rows as necessary[[3]](#footnote-4). If no exposure is foreseen and/or there is no need to consider local effects separately, then only indicate this and delete the table.]*

### Conclusion

*[Please give a brief conclusion on the acceptability of the scenarios.]*

### Non-professional users

### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Task/  Scenario | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each task/scenario where professional exposure is foreseen. If no exposure is foreseen and/or no systemic effect is observed, then only indicate this and delete the table.]*

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenarios combined | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each combination of scenarios assessed. If no combined exposure is foreseen, then only indicate this and delete the table.]*

### Local effects

**Risk Characterisation for local effects**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | Risk | | |
| Hazard category | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposures route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[Please include additional rows as necessary[[4]](#footnote-5). If no exposure is foreseen and/or there is no need to consider local effects separately, then only indicate this and delete the table.]*

### Conclusion

*[Please give a brief conclusion on the acceptability of the scenarios.]*

### Secondary (indirect) exposure as a result of use

### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenario | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each representative scenario where secondary (indirect) exposure of the general public is foreseen. If no exposure is foreseen and/or no systemic effect is observed, then only indicate this and delete the table.]*

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenarios combined | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each combination of scenarios assessed. If no combined exposure is foreseen, then only indicate this and delete the table.]*

### Local effects

**Risk Characterisation for local effects**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | Risk | | |
| Hazard category | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposures route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

*[Please include additional rows as necessary[[5]](#footnote-6). If no exposure is foreseen and/or there is no need to consider local effects separately, then only indicate this and delete the table.]*

### Conclusion

*[Please give a brief conclusion on the acceptability of the scenarios.]*

### Indirect exposure via food

*[Template structure to be further developed once the guidance is finalised.]*

### Production / formulation of active substance

*[Please include a section for each scenario where professional exposure is foreseen. If no professional exposure is foreseen, then only indicate this and delete the tables and text.]*

### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenario | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each scenario where professional exposure is foreseen. If no exposure is foreseen and/or no systemic effects observed, then only indicate this and delete the table.]*

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scenarios combined | Tier | AEL  mg/kg bw/d | Estimated uptake  mg/kg bw/d | Estimated uptake/ AEL  (%) | Acceptable  (yes/no) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please include a row for each combination of scenarios assessed. If no combined exposure is foreseen, then only indicate this and delete the table.]*

### Local effects

*[Please include an appropriate table for the assessment[[6]](#footnote-7). If no exposure is foreseen and/or there is no need to consider local effects separately, then only indicate this.]*

### Conclusion

*[Please give a brief conclusion on the acceptability of the scenarios.]*

### Aggregated exposure

*[Template structure to be further developed once the methodology has been developed.]*

## Risk characterisation for the environment

### Atmosphere

Conclusion: *[Please include a short conclusion on the assessment of the air compartment]*

### Sewage treatment plant (STP)

|  |  |
| --- | --- |
| Summary table on calculated PEC/PNEC values | |
|  | **PEC/PNECSTP** |
| Scenario 1 |  |
| Scenario n |  |

*[Please insert/delete rows as needed.]*

*Conclusion: [Please include a short text summarising the conclusion on the risk assessment]*

### Aquatic compartment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Summary table on calculated PEC/PNEC values | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 |  |  |  |  |
| Scenario n |  |  |  |  |

*[Please insert/delete rows as needed.]*

*Conclusion: [Please include a short text summarising the conclusion on the risk assessment]*

### Terrestrial compartment

|  |  |
| --- | --- |
| Calculated PEC/PNEC values | |
|  | **PEC/PNECsoil** |
| Scenario 1 |  |
| Scenario n |  |

*[Please insert/delete rows as needed.]*

*Conclusion: [Please include a short text summarising the conclusion on the risk assessment]*

### Groundwater

*[Please assess according to BPR Annex VI point 68 if the foreseeable concentration (PEC) of the active substance or any other substance of concern, or of relevant metabolites/ degradants or breakdown or reaction products in groundwater, exceeds the lower of the following concentrations: the maximum permissible concentration laid down by Directive 98/83/EC, or the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological, unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.]*

### Primary and Secondary poisoning

**Primary poisoning**

*[Where relevant please summarise here the outcome of the primary poisoning assessment].*

**Secondary poisoning**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Summary table on secondary poisoning | | | | | |
| Scenario | **Concentration** | **PECoral predator** | **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** | **PEC/PNEC**  **fish** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*[Please insert/delete rows as needed.]*

*Conclusion: [Please include a short text summarising the conclusion on primary and secondary poisoning]*

### Aggregated exposure (combined for relevant emission sources)

*[Please include an assessment if aggregated exposure is relevant based on the decision scheme developed by UBA (see Figure 1) and an overview on the results in the table below, if an aggregated exposure was conducted.]*



Figure 1: Decision tree on the need for estimation of aggregated exposure

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Summary table on calculated ΣPEC/PNEC values | | | | | | | | |
|  | ΣPEC/PNECSTP | ΣPEC/PNECwater | ΣPEC/PNECsed | ΣPEC/PNECseawater | ΣPEC/PNECseased | ΣPEC/PNECsoil | ΣPECGW | ΣPECair |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[Please insert/delete additional compartments if additional environmental compartments are relevant.]*

Conclusion: *[Please include a short text summarising the conclusion on the risk assessment based on aggregated exposure]*

N.B.: This part of the template will be further elaborated as soon as the guidance on aggregated exposure is available.

## Risk characterisation for the physico-chemical properties

*[Please include a conclusion on the risk characterisation]*

## Measures to protect man, animals and the environment

*[Please include a summary on relevant measures]*

# Appendices

## Appendix I: List of endpoints

### Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

|  |  |
| --- | --- |
| Active substance (ISO Name) |  |
| Product-type |  |

|  |  |
| --- | --- |
| Identity | |
| Chemical name (IUPAC) |  |
| Chemical name (CA) |  |
| CAS No |  |
| EC No |  |
| Other substance No. |  |
| Minimum purity of the active substance as manufactured (g/kg or g/l) |  |
| Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg) |  |
| Molecular formula |  |
| Molecular mass |  |
| Structural formula |  |

|  |  |
| --- | --- |
| **Physical and chemical properties** | |
| Melting point (state purity) |  |
| Boiling point (state purity) |  |
| Thermal stability / Temperature of decomposition |  |
| Appearance (state purity) |  |
| Relative density (state purity) |  |
| Surface tension (state temperature and concentration of the test solution) |  |
| Vapour pressure (in Pa, state temperature) |  |
| Henry’s law constant (Pa m3 mol -1) |  |
| Solubility in water (g/l or mg/l, state temperature) | pH 5 at \_\_\_ ⁰C:  pH 9 at \_\_\_ ⁰C:  pH [X] at \_\_\_ ⁰C: |
|  |
|  |
| Solubility in organic solvents (in g/l or mg/l, state temperature) |  |
| Stability in organic solvents used in biocidal products including relevant breakdown products |  |
| Partition coefficient (log POW) (state temperature) | pH 5 at \_\_\_ ⁰C:  pH 9 at \_\_\_ ⁰C:  pH [X] at \_\_\_ ⁰C: |
|  |
|  |
| Dissociation constant |  |
| UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) |  |
|  |  |
| **Explosives** | |
| Flammable gases |  |
| Flammable aerosols |  |
| Oxidising gases |  |
| Gases under pressure |  |
| Flammable liquids |  |
| Flammable solids |  |
| Self-reactive substances and mixtures |  |
| Pyrophoric liquids |  |
| Pyrophoric solids |  |
| Self-heating substances and mixtures |  |
| Substances and mixtures which in contact with water emit flammable gases |  |
| Oxidising liquids |  |
| Oxidising solids |  |
| Organic peroxides |  |
| Corrosive to metals |  |
| Desensitised explosives |  |
| Auto-ignition temperature(liquids and gases) |  |
| Relative self-ignition temperature for solids |  |
| Dust explosion hazard |  |

|  |  |
| --- | --- |
| **Classification and proposed labelling** | |
| with regard to physical hazards |  |
| with regard to human health hazards |  |
| with regard to environmental hazards |  |

### Chapter 2: Methods of Analysis

|  |  |
| --- | --- |
| **Analytical methods for the active substance** | |
| Technical active substance (principle of method) |  |
| Impurities in technical active substance (principle of method) |  |

|  |  |
| --- | --- |
| **Analytical methods for residues** | |
| Soil (principle of method and LOQ) |  |
| Air (principle of method and LOQ) |  |
| Water (principle of method and LOQ) |  |
| Body fluids and tissues (principle of method and LOQ) |  |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) |  |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) |  |

### Chapter 3: Impact on Human Health

|  |  |
| --- | --- |
| **Absorption, distribution, metabolism and excretion in mammals** | |
| Rate and extent of oral absorption: |  |
| Rate and extent of dermal absorption\*: |  |
| Rate and extent of inhalation absorption |  |
| Distribution: |  |
| Potential for accumulation: |  |
| Rate and extent of excretion: |  |
| Toxicologically significant metabolite(s) |  |

\* The dermal absorption value is applicable for the active substance and might not be usable in product authorization

|  |  |
| --- | --- |
| **Acute toxicity** | |
| Rat LD50 oral |  |
| Rat LD50 dermal |  |
| Rat LC50 inhalation |  |
| Skin corrosion/irritation |  |
| Eye irritation |  |
| Respiratory tract irritation |  |
| Skin sensitisation (test method used and result) |  |
| Respiratory sensitisation (test method used and result) |  |

|  |  |
| --- | --- |
| **Repeated dose toxicity** | |
| **Short term** |  |
| Species / target / critical effect |  |
| Relevant oral NOAEL / LOAEL |  |
| Relevant dermal NOAEL / LOAEL |  |
| Relevant inhalation NOAEL / LOAEL |  |
| **Sub-chronic** |  |
| Species/ target / critical effect |  |
| Relevant oral NOAEL / LOAEL |  |
| Relevant dermal NOAEL / LOAEL |  |
| Relevant inhalation NOAEL / LOAEL |  |
| **Long term** |  |
| Species/ target / critical effect |  |
| Relevant oral NOAEL / LOAEL |  |
| Relevant dermal NOAEL / LOAEL |  |
| Relevant inhalation NOAEL / LOAEL |  |

|  |  |
| --- | --- |
| **Genotoxicity** | |
| Carcinogenicity |  |
| Species/type of tumour |  |
| Relevant NOAEL/LOAEL |  |

|  |  |
| --- | --- |
| **Reproductive toxicity**  **Developmental toxicity** | |
| Species/ Developmental target / critical effect |  |
| Relevant maternal NOAEL |  |
| Relevant developmental NOAEL |  |

|  |  |
| --- | --- |
| **Fertility** | |
| Species/critical effect |  |
| Relevant parental NOAEL |  |
| Relevant offspring NOAEL |  |
| Relevant fertility NOAEL |  |

|  |  |
| --- | --- |
| **Neurotoxicity** | |
| Species/ target/critical effect |  |

|  |  |
| --- | --- |
| **Developmental Neurotoxicity** | |
| Species/ target/critical effect |  |

|  |  |
| --- | --- |
| **Immunotoxicity** | |
| Species/ target/critical effect |  |

|  |  |
| --- | --- |
| **Developmental Immunotoxicity** | |
| Species/ target/critical effect |  |

|  |  |
| --- | --- |
| **Other toxicological studies** | |
|  |  |

|  |  |
| --- | --- |
| **Medical data** | |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Summary | | | |
|  | **Value** | **Study** | **Safety factor** |
| AELlong-term |  |  |  |
| AELmedium-term |  |  |  |
| AELshort-term |  |  |  |
| ADI[[7]](#footnote-8) |  |  |  |
| ARfD |  |  |  |

|  |  |
| --- | --- |
| **MRLs** | |
| Relevant commodities |  |

|  |  |
| --- | --- |
| **Reference value for groundwater** | |
| According to BPR Annex VI, point 68 |  |

|  |  |
| --- | --- |
| **Dermal absorption** | |
| Study (in vitro/vivo), species tested |  |
| Formulation (formulation type and including concentration(s) tested, vehicle) |  |
| Dermal absorption values used in risk assessment |  |

### Chapter 4: Fate and Behaviour in the Environment

|  |  |
| --- | --- |
| **Route and rate of degradation in water** | |
| Hydrolysis of active substance and relevant metabolites/ degradants (DT50) (state pH and temperature) |  |
| pH 5 |  |
| pH 9 |  |
| Other pH: [indicate the value] |  |
| Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites/ degradants |  |
| Readily biodegradable (yes/no) |  |
| Inherent biodegradable (yes/no) |  |
| Biodegradation in freshwater |  |
| Biodegradation in seawater |  |
| Non-extractable residues |  |
| Distribution in water / sediment systems (active substance) |  |
| Distribution in water / sediment systems (metabolites/ degradants) |  |

|  |  |
| --- | --- |
| **Route and rate of degradation in soil** | |
| Mineralization (aerobic) |  |
| Laboratory studies (range or median, with number of measurements, with regression coefficient) |  |
| DT50lab (20°C, aerobic): |  |
| DT90lab (20°C, aerobic): |  |
| DT50lab (10°C, aerobic): |  |
| DT50lab (20°C, anaerobic): |  |
| Degradation in the saturated zone: |  |
| Field studies (state location, range or median with number of measurements) |  |
| DT50f: |  |
| DT90f: |  |
| Anaerobic degradation |  |
| Soil photolysis |  |
| Non-extractable residues |  |
| Relevant metabolites - name and/or code, % of applied a.i. (range and maximum) |  |
| Soil accumulation and plateau concentration |  |

|  |  |
| --- | --- |
| **Adsorption/desorption** | |
| Ka , Kd |  |
| Kaoc , Kdoc |  |
| pH dependence (yes / no) (if yes type of  dependence) |  |

|  |  |
| --- | --- |
| **Fate and behaviour in air** | |
| Direct photolysis in air |  |
| Quantum yield of direct photolysis |  |
| Photo-oxidative degradation in air | Latitude: ............. Season: ................. DT50 .............. |
| Volatilization |  |

|  |  |
| --- | --- |
| **Reference value for groundwater** | |
| According to BPR Annex VI, point 68 |  |

|  |  |
| --- | --- |
| **Monitoring data, if available** | |
| Soil (indicate location and type of study) |  |
| Surface water (indicate location and type of study) |  |
| Groundwater (indicate location and type of study) |  |
| Air (indicate location and type of study) |  |

### Chapter 5: Effects on Non-target Species

|  |  |  |  |
| --- | --- | --- | --- |
| Toxicity data for aquatic species (most sensitive species of each group) | | | |
| Species | **Time-scale** | **Endpoint** | **Toxicity** |
| Fish |  |  |  |
| Invertebrates |  |  |  |
| Algae |  |  |  |
| Microorganisms |  |  |  |

|  |  |
| --- | --- |
| **Effects on earthworms or other soil non-target organisms** | |
| Acute toxicity to ………………………………….. |  |
| Reproductive toxicity to ………………………… |  |

|  |  |
| --- | --- |
| **Effects on soil micro-organisms** | |
| Nitrogen mineralization |  |
| Carbon mineralization |  |

|  |  |
| --- | --- |
| **Effects on terrestrial vertebrates** | |
| Acute toxicity to mammals |  |
| Acute toxicity to birds |  |
| Dietary toxicity to birds |  |
| Reproductive toxicity to birds |  |

|  |  |
| --- | --- |
| **Effects on honeybees** | |
| Acute oral toxicity |  |
| Acute contact toxicity |  |

|  |  |
| --- | --- |
| **Effects on other beneficial arthropods** | |
| Acute oral toxicity |  |
| Acute contact toxicity |  |
| Acute toxicity to ………………………………….. |  |

|  |  |
| --- | --- |
| **Bioconcentration** | |
| Bioconcentration factor (BCF) |  |
| Depuration time (DT50) |  |
| Depuration time (DT90) |  |
| Level of metabolites (%) in organisms accounting for > 10 % of residues |  |

|  |  |
| --- | --- |
| Compartment | PNEC |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

*[Please insert relevant environmental compartments. Please include a similar table for relevant metabolites and/or degradation products.]*

### Chapter 6: Other End Points

## Appendix II: Human exposure calculations

## Appendix III: Environmental emission (and exposure) calculations

## Appendix IV: List of terms and abbreviations

## Appendix V: Overall reference list (including data owner and confidentiality claim)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Author(s) | Year | Section No / Reference No | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner | Data Identified as ‘relevant’ by the eCA[[8]](#footnote-9)  (Yes/No) | Applicability | |
|  |  |  |  |  |  |  | **CAR/RAR** | **CLH** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

## Appendix VI: Confidential information

*[Please provide under this section all the confidential information related to the case, including the reference specification, as separated documents. The template for the reference specification is available from ECHA website:* [*https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities*](https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities)*]*

## Appendix VII: Study summaries (relevant for the CLH proposal)

* Data from detailed study summaries needed for an independent and transparent assessment, to be included either
  + in Part A under each endpoint or
  + in Part D Appendix VII (e.g. by extracting from IUCLID for new active substances in BPR, please see the instructions for extracting study summaries from IUCLID in Appendix VII of Part D). In the link below, the [template of Annex I to the CLH report (with explanations)](https://echa.europa.eu/documents/10162/13563/clh_report_template_ai_en.doc/8ab5af56-a04a-44e8-98a7-816aa4e5787c) shows an example on how Appendix VII could be compiled and how each study could be presented individually under its own subchapter including the study reference, detailed study summary and results.
  + The format of the detailed study summary of an individual study is flexible, as long as the summary is clearly reported and under the correct hazard class (either in Part A or in in Part D Appendix VII).

*[Below are instructions for printing out study summaries from IUCLID as copied from the ECHA Manual: Functionalities of IUCLID 6, 2019:*

<https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf/c8c6b2d3-3ed6-e3b3-0834-4ac7ea4a65dc>

**Printing Study Summaries from IUCLID**

IUCLID 6 allows you to generate PDF documents and print the following files; Substance datasets, Mixture/Product datasets, Templates, Categories, Dossiers, Endpoint study records, Endpoint summary records, Reference substances, Literature references, Legal entity sites, Legal entities, Contacts, Annotations, Test Materials. There are some important points to note before generating a PDF and printing;

1. You can only generate a PDF and subsequently print if your IUCLID user account is assigned to a role which has been given permission to print. This is set in the Permissions tab of Roles in User management.

2. You cannot print more than one of the above files at any one time. If you wish to print two separate endpoint summaries for example, you will need to generate two individual PDFs.

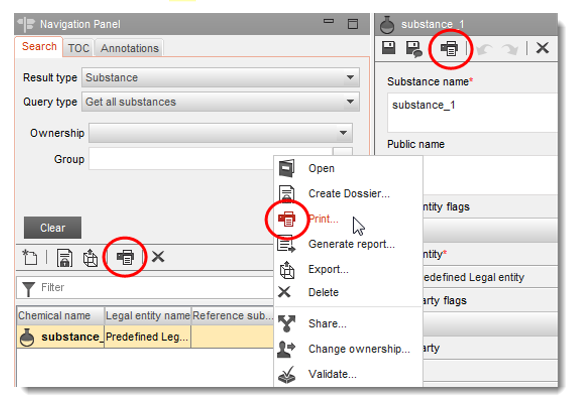
3. Any information which is flagged as confidential will be included in the PDF.

4. Any entities which are referenced by the dataset or document you print will also be included in the PDF. For instance, if you print a Category which is linked to a Legal entity, the Legal entity information will also be included in the PDF.

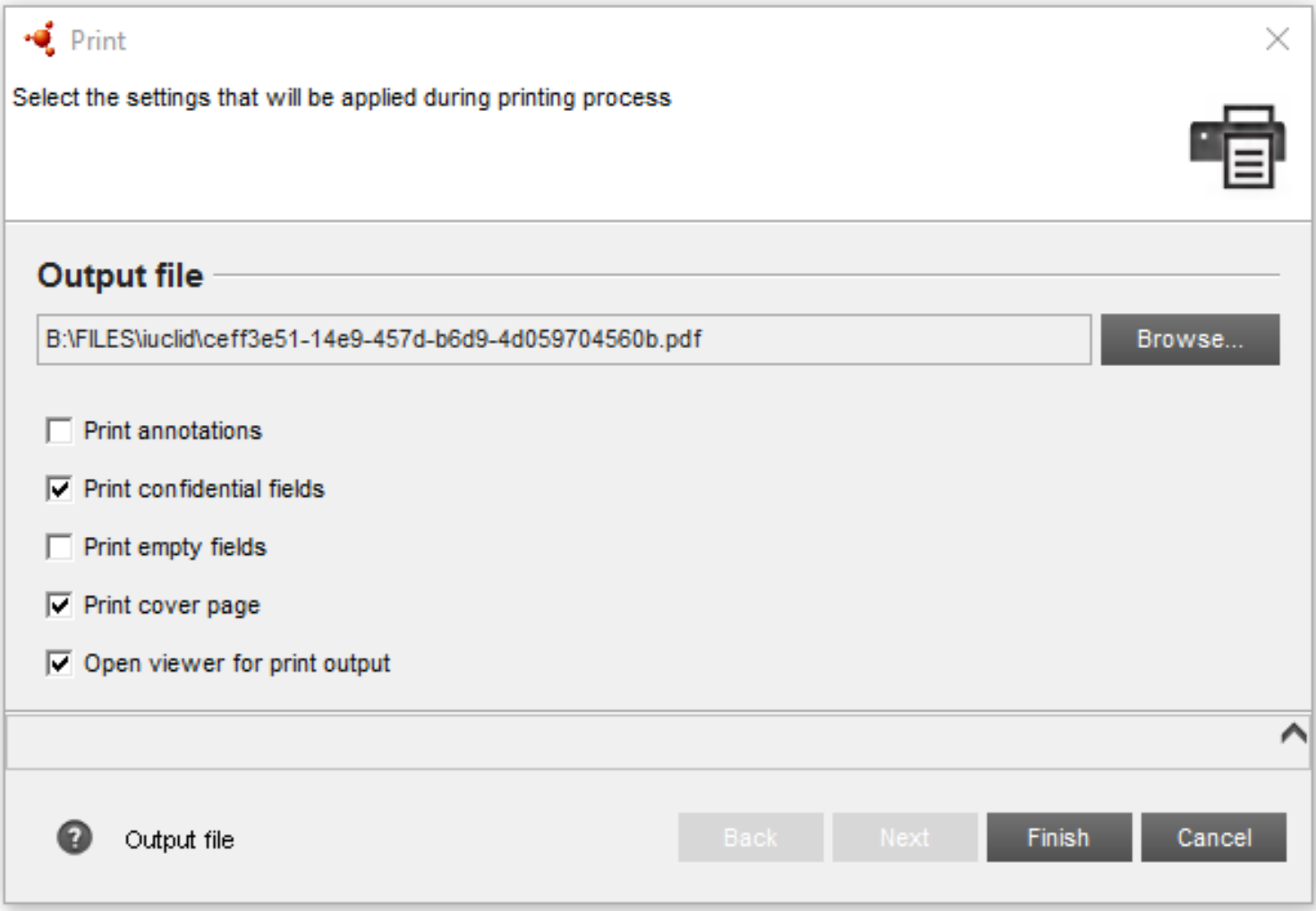
5. Inherited Endpoint study and summary records from a template cannot be printed individually, but are included in the PDF when printing an entire dataset.

**Print assistant**

To launch the printing function, click on the print icon, located as shown in the figure below. The menu is opened from within the *Navigation panel* by right-clicking on the search record of what is to be printed.



The Print assistant generates a PDF file in a single step, as shown in the figure below.



Under the heading *Output file* enter the path of the folder where the output will be saved. Click the *Browse* button to change the path.

There are five options:

1. Print annotations (by default unchecked): If you check this option, all the annotations of your dataset, document or entity will be included in the generated PDF.
2. Print confidential fields (by default unchecked): If you check this option, all the fields that are marked (confidential) in the dataset, document or entity will be included in the generated PDF. These fields are nothing to do with flagged fields.
3. Print empty fields (by default unchecked): If you check this option, all the empty fields of your dataset, document or entity will be included in the generated PDF.
4. Print cover page (by default checked): If you leave this box checked, the generated PDF will have a cover page which includes the following information;

a. Substance name

b. Legal Entity owner

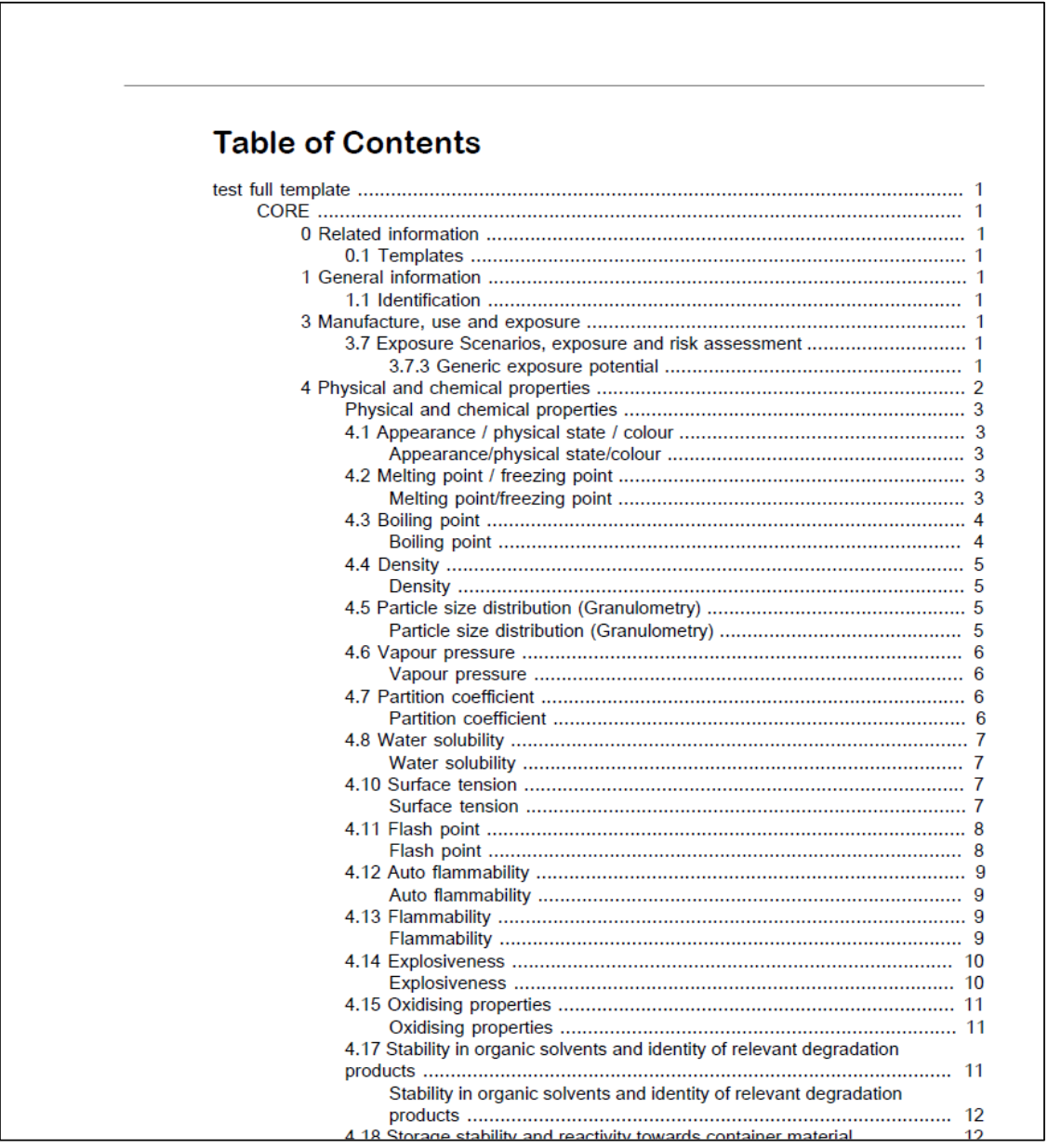
c. Printing date

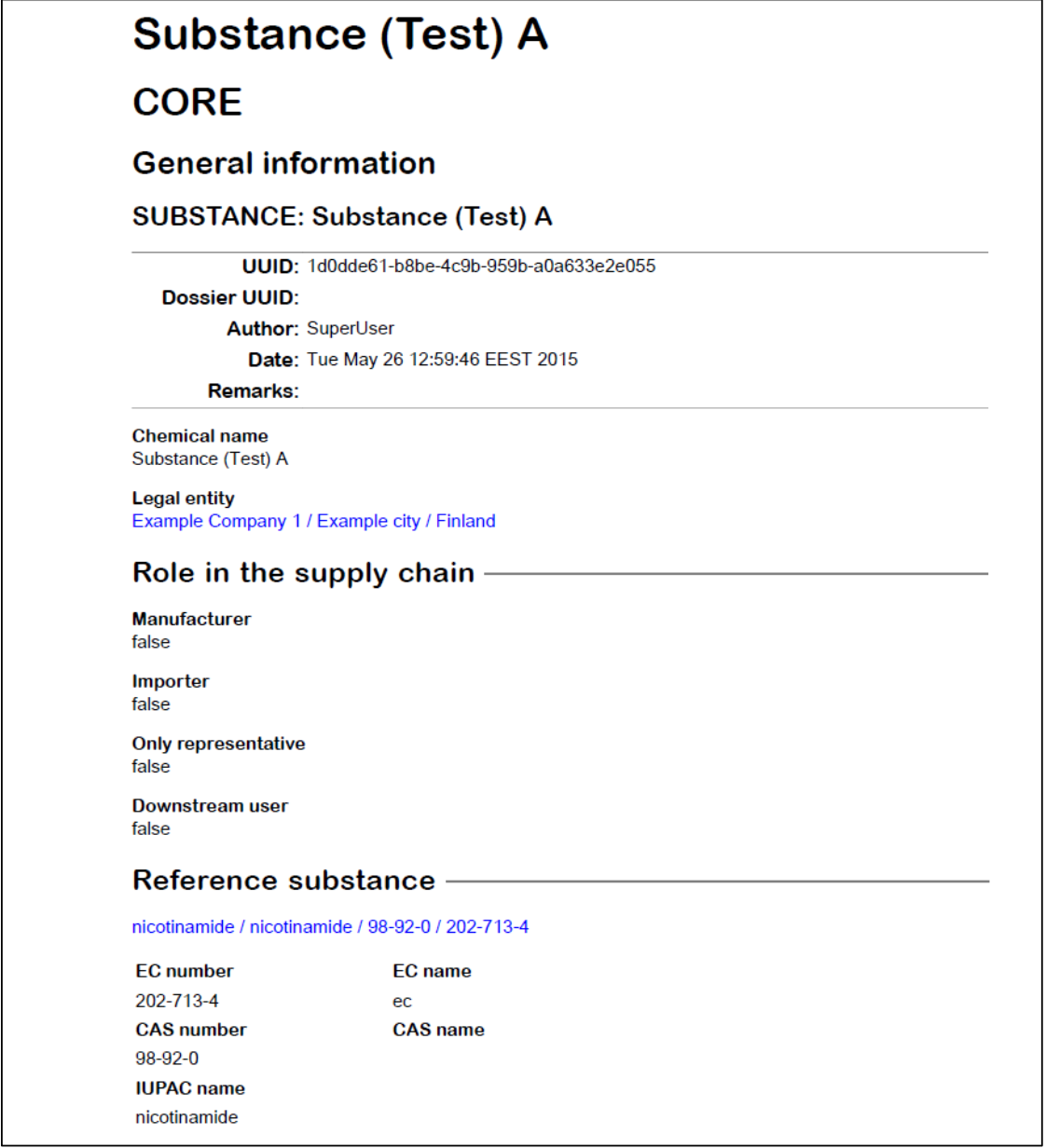
1. Open viewer for print output (by default checked): If you leave this box checked, the PDF will be opened automatically in the default PDF viewer for the host computer.

The print process is handled as a background job, as described in section *1.7.4 Background jobs*.

**Table of contents and structure of PDF**

In the generated PDF you will see underneath the cover page a table of contents. This will help you locate the information you wish to view. For large files such as datasets, the PDF will be structured according to the sections which contain information, see the examples below.





1. This table is a copy of the table in Chapter 8.3 of the Assessment Report. [↑](#footnote-ref-2)
2. Please, fill in the table for Risk Characterisation for local effects according to the ECHA Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment Chapter 4 and examples in Appendix 4-5. [↑](#footnote-ref-3)
3. Please, fill in the table for Risk Characterisation for local effects according to the ECHA Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment Chapter 4 and examples in Appendix 4-5. [↑](#footnote-ref-4)
4. Please, fill in the table for Risk Characterisation for local effects according to the ECHA Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment Chapter 4 and examples in Appendix 4-5. [↑](#footnote-ref-5)
5. Please, fill in the table for Risk Characterisation for local effects according to the ECHA Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment Chapter 4 and examples in Appendix 4-5. [↑](#footnote-ref-6)
6. Guidance for Human Health Risk Assessment Volume III, Part B. [↑](#footnote-ref-7)
7. If residues in food or feed. [↑](#footnote-ref-8)
8. Only relevant for the renewal of an active substance. Remove column for active substance approval and CLH process.

   For the identification of the relevant data, please see [CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95\_FINAL](https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a) [↑](#footnote-ref-9)