**CLH report**

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),**

**Annex VI, Part 2**

Chemical name:

**EC Number:**

**CAS Number:**

**Index Number:**

**Contact details for dossier submitter:**

**Version number: 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.**

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# IDENTITY OF THE SUBSTANCE

## Name and other identifiers of the substance

Table : Substance identity and information related to molecular and structural formula of the substance

|  |  |
| --- | --- |
| **Name(s) in the IUPAC nomenclature or other international chemical name(s)** | *[The Guidance for identification and naming of substances under REACH and CLP can be found at the following link:* [*http://echa.europa.eu/guidance-documents/guidance-on-reach*](http://echa.europa.eu/guidance-documents/guidance-on-reach) *]* |
| **Other names (usual name, trade name, abbreviation)** |  |
| **ISO common name (if available and appropriate)** | *[Usually only applicable for active substances in PPP or BP]* |
| **EC number (if available and appropriate)** |  |
| **EC name (if available and appropriate)** |  |
| **CAS number (if available)** |  |
| **Other identity code (if available)** | *[For example CIPAC number]* |
| **Molecular formula**  |  |
| **Structural formula** |  |
| **SMILES notation (if available)** |  |
| **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.]* |
| **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.]* |
| **Degree of purity (%) (if relevant for the entry in Annex VI)** | *[The minimum and maximum values should be specified.]* |

## Composition of the substance

Table 2: Constituents (non-confidential information)

| **Constituent****(Name and numerical identifier)** | **Concentration range (% w/w minimum and maximum in multi-constituent substances)** | **Current CLH in Annex VI Table 3 (CLP)**  | **Current self- classification and labelling (CLP)** |
| --- | --- | --- | --- |
|  |  |  |  |

*[Please insert rows according to the number of constituents in multi-constituent substances.]*

Table : Impurities (non-confidential information) if relevant for the classification of the substance

| **Impurity****(Name and numerical identifier)** | **Concentration range** **(% w/w minimum and maximum)** | **Current CLH in Annex VI Table 3 (CLP)**  | **Current self- classification and labelling (CLP)** | **The impurity contributes to the classification and labelling**  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

*[Please insert rows according to the number of impurities in the substance. If impurities are confidential information it is sufficient to state whether they contribute to the classification and labelling.]*

Table : Additives (non-confidential information) if relevant for the classification of the substance

| **Additive****(Name and numerical identifier)** | **Function** | **Concentration range** **(% w/w minimum and maximum)** | **Current CLH in Annex VI Table 3 (CLP)** | **Current self- classification and labelling (CLP)** | **The additive contributes to the classification and labelling** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

*[Please insert rows according to the number of additives in the substance. If additives are confidential information it is sufficient to state whether they contribute to the classification and labelling.]*

Table : Test substances (non-confidential information) (this table is optional)

| **Identification of test substance** | **Purity** | **Impurities and additives (identity, %, classification if available)** | **Other information** | **The study(ies) in which the test substance is used** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

*[Please give details on the test substance used in each study as far as known. Add rows as needed. 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].*

# PROPOSED HARMONISED CLASSIFICATION AND LABELLING

## Proposed harmonised classification and labelling according to the CLP criteria

Table : **For substance with an existing 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 | 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 submitters proposal | Existing Noor 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 emptyATE 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 Annex VI entry if agreed by RAC and COM | Existing Noor 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 statement 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 emptyATESCLM-factors | Add the resulting Notes without **Retain, Add, Modify** or **Remove** or leave empty |

Table 6: **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 emptyATE 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 : Reason for not proposing harmonised classification and status under consultation

| **Hazard class** | **Reason for no classification** | **Within the scope of consultation** |
| --- | --- | --- |
| **Explosives** |  | Yes/No |
| **Flammable gases (including chemically unstable gases)** |  | Yes/No |
| **Oxidising gases** |  | Yes/No |
| **Gases under pressure** |  | Yes/No |
| **Flammable liquids** |  | Yes/No |
| **Flammable solids** |  | Yes/No |
| **Self-reactive substances** |  | Yes/No |
| **Pyrophoric liquids** |  | Yes/No |
| **Pyrophoric solids** |  | Yes/No |
| **Self-heating substances** |  | Yes/No |
| **Substances which in contact with water emit flammable gases** |  | Yes/No |
| **Oxidising liquids** |  | Yes/No |
| **Oxidising solids** |  | Yes/No |
| **Organic peroxides** |  | Yes/No |
| **Corrosive to metals** |  | Yes/No |
| **Acute toxicity via oral route** |  | Yes/No |
| **Acute toxicity via dermal route** |  | Yes/No |
| **Acute toxicity via inhalation route** |  | Yes/No |
| **Skin corrosion/irritation** |  | Yes/No |
| **Serious eye damage/eye irritation** |  | Yes/No |
| **Respiratory sensitisation** |  | Yes/No |
| **Skin sensitisation** |  | Yes/No |
| **Germ cell mutagenicity** |  | Yes/No |
| **Carcinogenicity** |  | Yes/No |
| **Reproductive toxicity** |  | Yes/No |
| **Specific target organ toxicity-single exposure** |  | Yes/No |
| **Specific target organ toxicity-repeated exposure** |  | Yes/No |
| **Aspiration hazard** |  | Yes/No |
| **Endocrine disruption for HH** |  | Yes/No |
| **Hazardous to the aquatic environment** |  | Yes/No |
| **Endocrine disruption for ENV** |  | Yes/No |
| **PBT/vPvB** |  | Yes/No |
| **PMT/vPvM** |  | Yes/No |
| **Hazardous to the ozone layer** |  | Yes/No |

*[Please select one of the following reasons for not proposing harmonised classification for a hazard class or state if harmonised classification is proposed 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 ).]*

# 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.* *Discussion and agreement from previous formal EU assessments should also be included in the report and reflected in the sections discussing the data, if relevant.]*

# Justification that action is needed at community level

*[Justifications for all relevant hazard classes, other than CMR, ED, PBT, vPvB, PMT, vPvM and respiratory sensitisation, on why there is a need for action at the Community level, should be provided here. A substance that is an active substance in the meaning of Regulation EC 1107/2009 or Regulation (EU) No 528/2012 shall normally be subject to harmonised classification and labelling, and justification is not required. (Article 36 CLP Regulation)]*

*[Please choose A or B and delete the other option as well as the instructions in brackets]*

[A.] There is no requirement for justification that action is needed at Community level.

[B.] Justification that action is needed at Community level is required.

[In case of [B.]: Please choose one or more options from the list of reasons for a need for action at Community level. Please note that there may be different reasons for different hazard classes. In case you would have other reason/s, please provide the reasoning under “*Further detail on need of action at Community level”*.]

Reason for a need for action at Community level:

1. *Change in existing entry due to new data*
2. *Change in existing entry due to changes in the criteria*
3. *Change in existing entry due to new interpretation/evaluation of existing data*
4. *Differences in self-classification*
5. *Disagreement by DS with current self-classification*
6. *Requirement for harmonised classification by other legislation or process.*

Further detail on need of action at Community level

[*Please add further detail.*]

# Identified uses

*[It is recommended but not mandatory that a short description of the (main) uses of the substance is added, as this information is needed for the purposes of any dissemination concerning this CLH proposal on the ECHA website. The target organisms of PPP active substances may be relevant information for the assessment of ecotoxicity data set.]*

# Data sources

*[Please list the data sources and searches that were used to compile this CLH report.]*

# PHYSICOCHEMICAL PROPERTIES

Table : Summary of physicochemical properties

| **Property** | **Value** | **Reference**  | **Comment (e.g. measured or estimated)** |
| --- | --- | --- | --- |
| **Physical state at 20°C and 101,3 kPa** |  |  |  |
| **Melting/freezing point** |  |  |  |
| **Boiling point** |  |  |  |
| **Relative density** |  |  |  |
| **Vapour pressure** |  |  |  |
| **Surface tension** |  |  |  |
| **Water solubility** |  |  |  |
| **Partition coefficient n-octanol/water (KOW)** |  |  |  |
| **Partition coefficient n-octanol/air (KOA)** |  |  |  |
| **Flash point** |  |  |  |
| **Flammability** |  |  |  |
| **Explosive properties** |  |  |  |
| **Self-ignition temperature** |  |  |  |
| **Oxidising properties** |  |  |  |
| **Granulometry** |  |  |  |
| **Stability in organic solvents and identity of relevant degradation products** |  |  |  |
| **Dissociation constant** |  |  |  |
| **Viscosity** |  |  |  |

# EVALUATION OF PHYSICAL HAZARDS

## Explosives

Table : Summary table of studies on explosive properties

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

[Please insert/delete rows according to the number of studies. 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 information provided 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 : 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. 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 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.]*

## Oxidising gases

Table : Summary table of studies on oxidising gases

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on gases under pressure

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on flammable liquids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on flammable solids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on self-reactivity

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on pyrophoric liquids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on pyrophoric solids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on self-heating substances

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

[Please insert/delete rows according to the number of studies. 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 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 : 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. 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 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 : Summary table of studies on oxidising liquids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on oxidising solids

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

[Please insert/delete rows according to the number of studies. 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 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 : Summary table of studies on organic peroxides

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

[Please insert/delete rows according to the number of studies. 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 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 : 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. 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 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.]*

# TOXICOKINETICS (absorption, metabolism, distribution and elimination)

Table : Summary table of toxicokinetic studies

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

[Please insert/delete rows according to the number of studies. 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 toxicokinetic information on the proposed classification(s)

*[Please summarise the relevance of the toxicokinetic studies for the classification proposal.]*

# EVALUATION OF HEALTH HAZARDS

**Acute toxicity**

## Acute toxicity - oral route

Table : Summary table of animal studies on acute oral toxicity

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels, duration of exposure**  | **Value****LD50** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on acute oral toxicity

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for acute oral toxicity

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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 the classification and labelling for acute oral toxicity according to the CLP classification criteria.]*

## Acute toxicity - dermal route

Table : Summary table of animal studies on acute dermal toxicity

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels duration of exposure**  | **ValueLD50** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on acute dermal toxicity

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for acute dermal toxicity

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

## Acute toxicity - inhalation route

Table : Summary table of animal studies on acute inhalation toxicity

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance, , form and particle size (MMAD)** | **Dose levels, duration of exposure**  | **Value****LC50** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on acute inhalation toxicity

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for acute inhalation toxicity

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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 if 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 acute inhalation toxicity

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

## Skin corrosion/irritation

Table : Summary table of animal studies on skin corrosion/irritation

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels duration of exposure** | **Results****-Observations and time point of onset****-Mean scores/animal****-Reversibility** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on skin corrosion/irritation

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for skin corrosion/irritation

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

## Serious eye damage/eye irritation

Table : Summary table of animal studies on serious eye damage/eye irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels duration of exposure** | **Results****- Observations and time point of onset****- Mean scores/animal****- Reversibility** | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on serious eye damage/eye irritation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for serious eye damage/eye irritation

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

## Respiratory sensitisation

Table : Summary table of animal studies on respiratory sensitisation

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels, duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on respiratory sensitisation

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for respiratory sensitisation

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

## Skin sensitisation

Table : Summary table of animal studies on skin sensitisation

| **Method, guideline, deviations if any** | **Species, strain, sex, no/group** | **Test substance,**  | **Dose levels duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on skin sensitisation

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for skin sensitisation

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

## Germ cell mutagenicity

Table : Summary table of mutagenicity/genotoxicity tests in vitro

| **Method, guideline, deviations if any** | **Test substance,**  | **Relevant information about the study including rationale for dose selection (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of mutagenicity/genotoxicity tests in mammalian somatic or germ cells in vivo

| **Method, guideline, deviations if any** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data relevant for germ cell mutagenicity

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 germ cell mutagenicity

*[Please make a short summary of germ cell mutagenicity studies 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.]*

## Carcinogenicity

Table : Summary table of animal studies on carcinogenicity

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, dose levels duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on carcinogenicity

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for carcinogenicity

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 carcinogenicity

Table : Compilation of factors to be taken into consideration in the hazard assessment

| **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 excessive toxicity?** | **Route of exposure** | **MoA and relevance to humans** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. 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. Some additional important factors to be taken into consideration may 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.* *The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]*

### 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.]*

## Reproductive toxicity

### Adverse effects on sexual function and fertility

Table : Summary table of animal studies on adverse effects on sexual function and fertility

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, dose levels duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies on sexual function and fertility. Please note that also studies presented under other hazard classes, e.g. STOT-RE, may contain relevant information about the effects on sexual function and fertility and these results should be summarised in the table.* *The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]*

Table : Summary table of human data on adverse effects on sexual function and fertility

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for toxicity on sexual function and fertility

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

###  Comparison with the CLP criteria

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

###  Adverse effects on development

Table : Summary table of animal studies on adverse effects on development

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, dose levels duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on adverse effects on development

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for developmental toxicity

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 adverse effects on development

*[Please make a short summary of studies on adverse effects on development 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.]*

###  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.]*

###  Adverse effects on or via lactation

Table : Summary table of animal studies on effects on or via lactation

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, dose levels duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on effects on or via lactation

| **Type of data/report** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference**  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for effects on or via lactation

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference**  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

*[Please insert/delete rows according to the number of studies.* *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 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.]*

### 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.]*

### 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]*

## Specific target organ toxicity-single exposure

Table : Summary table of animal studies on STOT SE

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, route of exposure, dose levels, duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of human data on STOT SE

| **Type of data/report** | **Test substance**  | **Route of exposure****Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table : Summary table of other studies relevant for STOT SE

| **Type of study/data** | **Test substance**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 specific target organ toxicity – single exposure

*[Please make a short summary of the STOT SE 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. STOT SE.]*

### Conclusion on classification and labelling for STOT SE

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

## Specific target organ toxicity-repeated exposure

Table : Summary table of animal studies on STOT RE

*[Please note that also long-term studies on carcinogenicity, neurotoxicity or reproductive toxicity may provide evidence of specific target organ toxicity that should be reported here.]*

| **Method, guideline, deviations if any, species, strain, sex, no/group** | **Test substance, route of exposure, dose levels, duration of exposure**  | **Results** | **Reference** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

*[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]*

Table : Summary table of human data on STOT RE

| **Type of data/report** | **Test substance** | **Route of exposure****Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.

Table : Summary table of other studies relevant for STOT RE

| **Type of study/data** | **Test substance** | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 specific target organ toxicity – repeated exposure

*[Please make a short summary of the STOT RE 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 : Extrapolation of equivalent effective dose for toxicity studies of greater or lesser duration than 90 days [if adequate, otherwise please delete]

| **Study reference** | **Effective dose (mg/kg/d)** | **Length of exposure** | **Extrapolated effective dose when extrapolated to 90-day exposure** | **Classification supported by the study** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Comparison with the CLP criteria

*[Please perform a weight of evidence evaluation of all the study results 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. Consider also a potential need of setting a specific concentration limit.]*

## Aspiration hazard

Table : Summary table of evidence for aspiration hazard

| **Type of study/data** | **Test substance,**  | **Relevant information about the study (as applicable)** | **Observations** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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 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.]*

# Endocrine disruption for human health

*[ECHA Guidance on Application of the CLP Criteria, ECHA EFSA ED Guidance (2018) and the OECD GD 150 (including the OECD Conceptual Framework CF) provide useful supporting material for the ED assessment and reporting, particularly of EATS modalities.*

*It should be noted that there may be differences in legal requirements and data availability under different regulatory frameworks, however in all cases all available data should be reported with sufficient details.*

*Please delete all the tables and sub-sections that are not relevant for your dossier. Please amend/delete the suggested table headings below as necessary. Separate tables can be provided for endocrine activity related to different modalities. Please report also parameters sensitive to, but not diagnostic of EATS such as effects on brain weight etc., in the EATS table. Data on other relevant substances, such as analogues, if relevant, should be included in the relevant tables together with information on the substance subject to the classification proposal. Available (optional) supportive/illustrative material for the ED assessment can be provided in an Appendix to the CLH proposal.]*

##  Evidence on EATS[[1]](#footnote-2) and other modalities

### Summary tables of evidence for Adversity – EATS and other modalities

*[It should be noted that there are other endocrine (i.e. non-EATS) modalities. Although the existing knowledge for those modalities is not as advanced as for the EATS modalities, it may, in some cases, be already possible to reach a conclusion on non-EATS mediated endocrine disruptors, e.g. where literature data provide information, which can be linked to adverse effects measured in reliable tests. Such information should be reported in separate tables applying the same assessment principles as for EATS modalities.. EAS and T modalities are proposed to be included together in one table, however, if the data suggests differentiating for example T modality, a separate table for T modality can be included.]*

Table 70: Evidence for adversity

*[Please report all relevant evidence on adversity for all modalities here, including in vivo, , read across and possible New Approach Methods (NAMs) etc., if not already reported in another section. When necessary, additional tables can be included. Differentiation of modalities in separate tables may be applied, particularly for substances with a large dataset.*

*When studies are already reported in another section, please refer to the relevant reference and table number/ page of this dossier where further information on the study can be found. However, all the ED related effects and quality of the study should be indicated shortly in this table.]*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species, strain, sex, no/group, cell line when applicable (NAMs), vehicle if relevant, and reliability** | **Test substance, dose/concentration levels, duration and lifestage of exposure**(*e.g., gestational, postnatal, adult or multigenerational*) | **Endocrine modality (E, A, S, T, other, please also separate if sensitive to but not diagnostic of EATS)** | **Type of effects related to ED modality** | **Effect levels and magnitude (excessive: yes or no) of general systemic (parental) toxicity** | **Results (positive and negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** *(if the study is already reported under another section, please refer to the relevant table/text here)* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Evaluation and conclusion on adverse effects

*[Please include the main findings in a text form. This applies only to studies summarised in Table 70.]*

### Summary tables of evidence for Endocrine activity – EATS and other modalities

*[When a study provides information on both endocrine activity and adversity, please describe the study in detail only once in a table for adverisity and include a cross reference to this study in the relevant table on endocrine activity. Parameters provide mechanistic information or are ED mediated should be shortly described under ndocrine activity.]*

**Table** 71**: Evidence for endocrine activity in silico**

*[Please include information on QSAR prediction, modelling and binding in this table, if available. Please assess the information and include the main findings in a text form below the tables.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Model and version of the QSAR, applicability domain, reliability** | **Endocrine modality**  | **Type of effects related to EDmodality** | **Results (positive/negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

**Table** 72**: Evidence for endocrine activity in vitro**

*[Please assess the studies and include the main findings in a text form below the tables.]*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species/receptor origin or assay, cell line type, vehicle used, pos and neg controls used, reliability** | **Test substance, conc. or conc. range, duration of exposure** | **Endocrine modality**  | **Type of effects related to ED modality** | **Results (positive/negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

**Table** 73**: Evidence for endocrine activity in vivo**

*[Please describe the effects that are ED mediated, even if already reported under adversity, or refer to the effects reported in the table on adversity, since those effects can provide indications of endocrine activity (e.g. estrous cycle disruption, see details in ECHA EFSA ED guidance section 4.3). Please assess the studies and include the main findings in a text form below the table. Please also give indication about the use of a specific inhibitor or knock-out species.]*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species, strain, sex, no/group, , vehicle if relevant, and reliability** | **Test substance, dose/concentration levels, duration and lifestage of exposure**(*e.g., gestational, postnatal, adult or multigenerational*) | **Endocrine modality (E, A, S, T, other)** | **Type of effects related to ED modality** | **Effect levels and magnitude (excessive: yes or no) of general systemic (parental) toxicity** | **Results (positive andnegative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** *(if the study is already reported under another section, please refer to the relevant table/text here)* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Evaluation and conclusion on endocrine activity

*[Include the main findings in a text form.]*

### Integration of evidence for Endocrine Activity and Adversity – EATS and other modalities

*[Please provide a WoE-summary of the endocrine activity and adversity and assessment how they are integrated in a text form and/or in a table as proposed below. See Section 3.3 of the ECHA EFSA ED Guidance for further information. A conclusion for EATS and other modalities should be derived.]*

**Table** 74 **(optional): Assembling and integration of evidence for endocrine activity and adversity**

[*Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.*]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Type of study/evidence** | **Lines of evidence (effect target)** | **Species** | **Exposure period** | **Route of exposure** | **Effect dose e.g. mg/kg/d**  | **Oberved effects**  | **Effect observed only in presence of excessive general systemic (parental) toxicity (Y/N)** | **Assessment of evidence** | **Assessment of integrated evidence** | **Modality** |
| **Integrated evidence for endocrine activity** | *Example: In vivo mechanistic* | *Hormonal changesin ERα* | *Rat* |  |  |  | *Dose depended decrease* |  | *Hormone changes observed in twp species dose dependent manner* | *Overall positive for endocrine activity* | *E* |
| *Mice* |  |  |  | *Dose depended decrease* |  |
| **Integrated evidence for adversity** |  |  |  |  |  |  |  |  |  |  |  |

## Mode of Action (MoA) analysis

*[Guidance on how to postulate and conclude on MoA(s), assess the biological plausibility of a link between endocrine activity and adverse effects as well as to identify which further information could help to clarify the postulated MoA(s) is provided in Section 3.5 of the ECHA/EFSA ED guidance. ֜Biologically plausible link’ means the correlation between one or a series of biological processes leading to an adverse effect and an endocrine activity, where the correlation is consistent with existing knowledge. In those cases where the evidence does not support an ED MoA, please report this shortly here.*

*The postulated MoAs can be presented based on general scientific knowledge. The biologically plausible link does not need to be demonstrated with substance specific data but can be explained e.g. through an existing AOP.*

*Please amend/repeat/delete the suggested table headings below as necessary. Separate tables should be provided for different endocrine modes of action. The format presenting the information in a clear and structured way by Browne et al (2017) or by chapters 2.1.4 and 2.2.4 of Appendix I of the pesticide administrative guidance (doi: 10.2903/sp.efsa.2019.EN-1612) may be used. Please provide a summary in a text, table and/or a figure format. Empirical support for dose-response/incidence and temporal concordance for the key event relationship, essentiality (if data are available), consistency, analogy and specificity of the key event may be reported as described in Section 3.5 of the ECHA/EFSA ED guidance (see example Table 8) in a table form.*

*Human relevance of MoA is assumed by default unless there is indication that this may not be the case. Hence, only if there is such indication, assessment of relevance for humans of the postulated MoA(s) needs to be carried out here. Cf. sections 3.5. & 3.3. of ECHA EFSA ED guidance.]*

### Summary tables of Mode of Action analysis and biological plausibility

**Table** 75**: Summary table on key events for mode of action and analysis of biological plausibility (optional).**

*[Summarise here the hypothesis and provide a brief description of key event (KE) and supportive evidence for biological plausibility. Some rows may be empty, depending on the level of knowledge available.]*

|  |
| --- |
| Summary of hypothesis: *e.g. estrous cycle disturbance* |
|  | **Brief description of key event (KE)** | **Supporting evidence from same or analogue substance or general knowledge.** |
| e.g. MIE | *e.g. Molecular: Activation of estrogen receptor* |  |
| KE1 | *e.g. Increased estrogenic activity* |  |
| KE2 | *e.g. Disturbed estrous cycle*  |  |
| AO1 | *e.g. reduced fertility*  |  |
| AO2 | *e.g. Decreased number of pups* |  |

### Assessment of possible other modes of action

*[Please describe here possible non-endocrine modes of action. In case EATS-mediated parameters are affected, a comparative MoA analysis should be provided.]*

### Conclusion on the Mode of Action analysis and biological plausibility

*[Consider guidance provided in section 3.5 of the ECHA EFSA ED guidance.]*

## Short summary and overall relevance of the provided information on endocrine disruption for human health

*[Please make a short summary of the evidence for endocrine disruption and conclude on the relevance of the provided data. Please summarise clearly but shortly the evidence for adversity, endocrine activity and the biological plausibility / MoA analysis]*

## Comparison with the CLP criteria

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

## Conclusion on classification and labelling for endocrine disruption for human health

# EVALUATION OF AQUATIC HAZARDS UNDER CLP ANNEX I, 4.1

## Rapid degradability of organic substances (CLP Annex I, 4.1)

Table 76: Summary of relevant information on rapid degradability

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

[If relevant, link to information that may be available under a following section of the CLH report template.]

### Ready biodegradability

*[Please provide a short overall summary of the reported tests measuring ready biodegradability and conclude on the relevance of the provided information.]*

### BOD5/COD

*[Please provide a short overall summary of the reported BOD5/COD tests and conclude on the relevance of the provided information.]*

### Hydrolysis

*[Please provide a short overall summary of the reported hydrolysis data and conclude on the relevance of the provided information.]*

### Other convincing scientific evidence

*[Please provide a short overall summary of the other reported convincing scientific evidence and conclude on the relevance of the provided information.]*

#### Field investigations and monitoring data (if relevant for the hazard class)

*[Please provide a short overall summary of the reported field investigations and monitoring data and conclude on the relevance of the provided information.]*

#### Inherent and enhanced ready biodegradability tests

*[Please provide a short overall summary of the reported inherent and enhanced biodegradability test data and conclude on the relevance of the provided information.]*

#### Water, water-sediment and soil degradation data (including simulation studies)

*[Please provide a short overall summary of the reported water, water-sediment and/or soil degradation data and conclude on the relevance of the provided information.]*

#### Photochemical degradation

*[Please provide a short overall summary of the reported photochemical degradation data and conclude on the relevance of the provided information.]*

## Environmental transformation of metals or inorganic metals compounds

Table : Summary of relevant information on rapid environmental transformation

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Summary of data/information on environmental transformation

*[Please provide a short overall summary of the reported environmental transformation of metals and inorganic metal compounds and conclude on the relevance of the provided information.]*

## Environmental fate and other relevant information

*[Note that in this section only information that does not fit under any other heading in chapter 11 should be reported. Please provide a short overall summary of other relevant information that is considered relevant in assessing aquatic toxicity, bioaccumulation or degradation. Such information could be e.g. the reported environmental fate properties if considered relevant in evaluating the toxicity data (e.g. volatilisation and adsorption).]*

## Bioaccumulation (CLP Annex I, 4.1)

Table : Summary of relevant information on bioaccumulation

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

[If relevant, link to information that may be available under a following section of the CLH report template.]

### Estimated bioaccumulation

*[Please provide a short overall summary of the reported estimated bioaccumulation (e.g. computed estimates of log Kow or equivalent) and conclude on the relevance of the provided information]*

### Measured partition coefficient and bioaccumulation test data

*[Please provide a short overall summary of the reported measured partition coefficient and bioaccumulation testing data (e.g. fish bioaccumulation studies) and conclude on the relevance of the provided information.]*

## Acute aquatic hazard (CLP Annex I, 4.1)

Table : Summary of relevant information on acute aquatic toxicity

| **Method/ Study type** | **Test material and purity** | **Results1** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1 Indicate if the results are based on the measured or on the nominal concentration

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Acute (short-term) toxicity to fish

*[Please make an overall summary of available acute toxicity studies to fish and conclude on the relevance of the provided data.]*

### Acute (short-term) toxicity to aquatic invertebrates

*[Please make an overall summary of available acute toxicity studies to aquatic invertebrates and conclude on the relevance of the provided data.]*

### Acute (short-term) toxicity to algae or other aquatic plants

*[Please make an overall summary of available acute toxicity studies to algae or other aquatic plants and conclude on the relevance of the provided data.]*

### Acute (short-term) toxicity to other aquatic organisms

*[Please make an overall summary of available acute toxicity studies to other aquatic organisms – if relevant for C&L - and conclude on the relevance of the provided data.]*

## Long-term aquatic hazard (CLP Annex I, 4.1)

Table 80: Summary of relevant information on chronic aquatic toxicity

| **Method/ Study type** | **Test material and purity** | **Results1** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1 Indicate if the results are based on the measured or on the nominal concentration

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Chronic toxicity to fish

*[Please make an overall summary of available chronic toxicity studies to fish and conclude on the relevance of the provided data.]*

### Chronic toxicity to aquatic invertebrates

*[Please make an overall summary of available chronic toxicity studies to aquatic invertebrates and conclude on the relevance of the provided data.]*

### Chronic toxicity to algae or other aquatic plants

*[Please make an overall summary of available chronic toxicity studies to algae or other aquatic plants and conclude on the relevance of the provided data.]*

### Chronic toxicity to other aquatic organisms

*[Please make an overall summary of available chronic toxicity studies to other aquatic organisms – if relevant for C&L - and conclude on the relevance of the provided data.]*

## Comparison with the CLP criteria (CLP Annex I, 4.1)

### Acute aquatic hazard

*[Please compare the information regarding acute toxicity in aquatic organisms with the CLP classification criteria for acute (short-term) aquatic hazard classification.]*

### Long-term aquatic hazard (including bioaccumulation potential and degradation)

*[Please compare the information regarding*

* *chronic toxicity in aquatic organisms with the CLP classification criteria for long-term aquatic hazard. If no adequate chronic toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants), consider using surrogate approach (Figure 4.1.1 and Table 4.1.0 in Annex I of CLP).*
* *bioaccumulation with the CLP classification criteria to conclude on potential for bioaccumulation of the substance.*
* *degradation with the CLP classification criteria to conclude on rapid degradability of the substance.]*

## CONCLUSION ON CLASSIFICATION AND LABELLING FOR AQUATIC HAZARDS

*[Please provide separate conclusions on classification for acute and chronic aquatic hazards. Separate M-factors should be provided for Aquatic Acute 1 and Aquatic Chronic 1 classifications.]*

# Endocrine disruption for the environment

*[ECHA Guidance on Application of the CLP Criteria, ECHA EFSA ED Guidance (2018) and the OECD GD 150 (including the OECD Conceptual Framework CF) provide useful supporting material for the ED assessment and reporting, particularly of EATS modalities.*

*It should be noted that there may be differences in legal requirements and data availability under different regulatory frameworks, however in all cases all available data should be reported with sufficient details.*

*Please delete all the tables and sub-sections that are not relevant for your dossier. Please amend/delete the suggested table headings below as necessary. Separate tables can be provided for endocrine activity related to different modalities. Please report also parameters sensitive to, but not diagnostic of EATS such as effects on brain weight etc., in the EATS table. Data on other relevant substances, such as analogues, if relevant, should be included in the relevant tables together with information on the substance subject to the classification proposal. Available (optional) supportive/illustrative material for the ED assessment can be provided in an Appendix to the CLH proposal.]*

##  Evidence on EATS[[2]](#footnote-3) and other modalities

### Summary tables of evidence for Adversity – EATS and other modalities

*[Evidence should ideally be assembled, assessed, integrated and reported as described in section 3.3. of the ECHA EFSA ED guidance 2018. Information according to levels 3, 4 and 5 (potentially also level 1 ) of the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals (revised version 2018) may be used to inform on adverse endocrine related effects of the substance whereas information in accordance with levels 2 to 5 (potentially also level 1) of the Conceptual Framework may be used to inform on endocrine activity exerted by the substance.*

*The EAS and T (i.e. EATS) modalities are currently the pathways for which there is a relatively good mechanistic understanding of how substance-induced perturbations may lead to adverse effects via an endocrine disrupting MoA. In addition, only for these modalities there are at present standardised test guidelines for in vivo and in vitro testing available where there is broad scientific agreement on the interpretation of the effects observed on the investigated parameters. However, there are other endocrine (i.e. non-EATS) modalities. Although the existing knowledge for those modalities is not as advanced as for the EATS modalities, it may, in some cases, be already possible to reach a conclusion on non-EATS mediated endocrine disruptors, e.g. where literature data provide information, which can be linked to adverse effects measured in reliable tests. Such information should be reported in a separate tables applying the same assessment principles as for EATS modalities (e.g. Chapter 3 of ECHA EFSA ED guidance). EAS and T modalities are proposed to be included together in one table, however, if the data suggests differentiating for example T modality, a separate table for T modality can be included.]*

Table 81**: Evidence for adversity**

*[Please report all relevant evidence on adversity for all modalities here, including in vivo, read across and possible New Approach Methods (NAMs) etc., if not already reported in another section. When necessary, add tables. Please assess the studies and include the main findings in a text form below the table. For the studies already reported under ED HH, a reference to the relevant study and table is sufficient. Please still assess the evidence related to adversity for population relevance below this table. For subastances with a large dataset, differentiation of modalities in separate tables may be applied.*

*When studies are already reported in another section, please refer to the relevant reference and table number/ page of this dossier where further information on the study can be found. However, all the ED related effects and quality of the study should be indicated shortly in this table.]*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species, sex, no/group, cell line when applicable (NAMs), vehicle if relevant, and reliability** | **Test substance, dose/concentration levels, duration and lifestage of exposure**(*e.g., embryo, larval, juvenile, , adult or multigenerational*) | **Endocrine modality (E, A, S, T, other)** | **Type of effects related to ED modality** | **Effect levels and magnitude (excessive: yes or no) of general systemic (parental) toxicity** | **Results (positive and negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** *(if the study is already reported under another section, please refer to the relevant table/text here)* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Evaluation and conclusion on adverse effects

*[Please include the main findings in a text form. This applies only to studies summarised in Table 81.]*

### Summary tables of evidence for Endocrine activity – EATS and other modalities

*[When a study provides information on both endocrine activity and adversity, please describe the study in detail only once in a table for adverisity and include a cross reference to this study in the relevant table on endocrine activity. In this case, parameters which provide mechanistic information or are ED mediated should be shortly described under endocrine activity.]*

Table 82**: Evidence for endocrine activity in silico**

*[Please include information on QSAR prediction, modelling and binding in this table. Please assess the information and include the main findings in a text form below the table if needed.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Model and version of the QSAR, applicability domain, reliability** | **Endocrine modality**  | **Type of effects related to EDmodality** | **Results (positive/negative findings from each study)** | **Observations/ interpretation / weight of the dat** | **Reference** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table 83**: Evidence for endocrine activity in vitro**

*[Please assess the studies and include the main findings in a text form below the table if needed.]*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species/receptor origin or assay, cell line type, vehicle used, pos and neg controls used, reliability** | **Test substance, conc. or conc. range, duration of exposure** | **Endocrine modality**  | **Type of effects related to ED modality** | **Results (positive/negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

Table 84: **Evidence for endocrine activity in vivo**

*[Please also describe the effects that are ED mediated, even if already reported under adversity, or refer to the effects reported in the table on adversity, since those effects can provide indications of endocrine activity (e.g. estrous cycle disruption, see details in ECHA EFSA ED guidance section 4.3). Please assess the studies and include the main findings in a text form below the table if needed. Please also give indication about the use of a specific inhibitor or knock-out species.]*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Method, guideline, deviations if any, species, sex, no/group, vehicle if relevant, and reliability** | **Test substance, dose/concentration levels, duration and lifestage of exposure**(*e.g., embryo, larval, juvenile, , adult or multigenerational*) | **Endocrine modality (E, A, S, T, other)** | **Type of effects related to ED modality** | **Effect levels and magnitude (excessive: yes or no) of general systemic (parental) toxicity** | **Results (positive and negative findings from each study)** | **Observations/ interpretation / weight of the data** | **Reference** *(if the study is already reported under another section, please refer to the relevant table/text here)* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Integration of evidence for Endocrine Activity and Adversity – EATS and other modalities

*[Please provide a WoE-summary of the endocrine activity and adversity and assessment how they are integrated in a text form and/or in a table as proposed below. See Section 3.3 of the ECHA EFSA ED Guidance for further information. A conclusion for EATS and other modalities should be derived.]*

Table 85 **(optional): Assembling and integration of evidence for endocrine activity and adversity**

[*Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.*]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Type of study/evidence** | **Lines of evidence (effect target)** | **Species** | **Exposure period** | **Route of exposure** | **Effect concentration e.g. mg/kg/d**  | **Oberved effects**  | **Effect observed only in presence of excessive general systemic (parental) toxicity (Y/N)** | **Assessment of evidence** | **Assessment of integrated evidence** | **Modality** |
| **Integrated evidence for endocrine activity** | *Example: In vivo mechanistic* | *VTG in females* | *Pimephales promelas* | *3 weeks* | *water* | *0.5* | *Dose depended decrease* | *N* | *Sufficient: concentration-related changes in VTG* | *Overall positive for endocrine activity* | *S* |
|  *Pimephales promelas* | *3 weeks* | *water* | *1* | *decrease only at the highest concentration* | N |
| **Integrated evidence for adversity** | Example: EATS mediate parameters | Specific female histopathology | *Pimephales promelas* | 36 | water | 0.6 | Only at the highest does | N | Supportinve evidence | Overall positive evidence for adversity | S |
| Sensitive to, but not diagnostic of, EATS | fecundity | *Pimephales promelas* | 3 | water | 1 | Dose dependant decrease | N | Dose related decrease in fecundity |
| *Pimephales promelas* | 3 | water | 0.5 | Dose dependant decrease | N | Dose related decrease in fecundity |

## Mode of Action (MoA) analysis

*[Guidance on how to postulate and conclude on MoA(s), assess the biological plausibility of a link between endocrine activity and adverse effects as well as to identify which further information could help to clarify the postulated MoA(s) is provided in Section 3.5 of the ECHA/EFSA ED guidance. ֜Biologically plausible link’ means the correlation between one or a series of biological processes leading to an adverse effect and an endocrine activity, where the correlation is consistent with existing knowledge. In those cases where the evidence does not support an ED MoA, please report this shortly here.*

*The postulated MoAs can be presented based on general scientific knowledge. The biologically plausible link does not need to be demonstrated with substance specific data but can be explained e.g. through an existing AOP.*

*Please amend/repeat/delete the suggested table headings below as necessary. Separate tables should be provided for different endocrine modes of action. The format presenting the information in a clear and structured way by Browne et al (2017) or by chapters 2.1.4 and 2.2.4 of Appendix I of the pesticide administrative guidance (doi: 10.2903/sp.efsa.2019.EN-1612) may be used. Please provide a summary in a text, table and/or a figure format. Empirical support for dose-response/incidence and temporal concordance for the key event relationship, essentiality (if data are available), consistency, analogy and specificity of the key event may be reported as described in Section 3.5 of the ECHA/EFSA ED guidance (see example Table 8) in a table form.*

### Summary tables of Mode of Action analysis and biological plausibility

Table 86: **Summary table on key events for mode of action and analysis of biological plausibility (optional).**

*[Summarise here the hypothesis and provide a brief description of key event (KE) and supportive evidence for biological plausibility. Some rows may be empty, depending on the level of knowledge available.]*

|  |
| --- |
| Summary of hypothesis: *e.g. aromatase inhibition leading to reproductive dysfunction* |
|  | **Brief description of key event (KE)** | **Supporting evidence from same or analogue substance or general knowledge.** |
| e.g. MIE | *e.g. Molecular: aromatase inhibition* |  |
| KE1 | *e.g. reduced 17beta-estradiol concentrations* |  |
| KE2 | *e.g. reduction synthesis vitellogenin*  |  |
| AO1 | *e.g. reduced fecundity and spawning* |  |
| AO2 | *e.g. Decreased population growth rate* |  |

### Assessment of possible other modes of action

*[Please describe here possible non-endocrine modes of action. In case EATS-mediated parameters are affected, a comparative MoA analysis should be provided.]*

### Conclusion on the Mode of Action analysis and biological plausibility

*[Consider guidance provided in section 3.5 of the ECHA EFSA ED guidance.]*

## Short summary and overall relevance of the provided information on endocrine disruption for the environment

*[Please make a short summary of the evidence for endocrine disruption and conclude on the relevance of the provided data. Please summarise clearly but shortly the evidence for adversity, endocrine activity and the biological plausibility / MoA analysis]*

## Comparison with the CLP criteria

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

## Conclusion on classification and labelling for endocrine disruption for the environment

# Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent, Very Bioaccumulative (vPvB) properties under CLP Annex I, 4.3

*[Please use the following paragraphs (modified as necessary) to reflect the weight-of-evidence you have used: A weight-of-evidence determination according to the provisions of Annex I, Section 4.3. of CLP Regulation is used to classify the substance as PBT/vPvB. Higher tier information should come first, followed by other supportive elements. All available information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) will be considered together in a weight-of-evidence approach.* *Information on ingredient substances (constituents/ degradation or transformation products/ impurities/ additives/ etc.) and any relevant group substance properties belonging to the same category, if relevant, must be recorded under the relevant sub-heading. Further instructions on how to report such information on ingredient substances will be included in the CLP Guidance, currently under development, as well as the weighing of the different elements within the weight-of-evidence determination. Please delete all the tables and sub-sections that are not relevant for your dossier. Please amend/delete the suggested table headings below as necessary. Separate tables can be provided for different types of information].*

## Persistence under CLP Annex I, 4.3

*[Please refer to any information that may already be available under a previous section of the CLH report template (e.g. on aquatic hazards). Such a reference may be sufficient and no repetition of the same information is needed].*

Table 87**. Summary of relevant information on persistence under CLP Annex I, 4.3**

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
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|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

### Water, water-sediment and soil degradation data (including simulation studies)

*[Please provide a short overall summary of the reported water, water-sediment and/or soil degradation data and conclude on the relevance of the provided information.]*

### Ready biodegradability tests

*[Please provide a short overall summary of the reported tests measuring ready biodegradability and conclude on the relevance of the provided information.]*

### Inherent biodegradability tests

*[Please provide a short overall summary of the reported inherent biodegradability test data and conclude on the relevance of the provided information.]*

### Enhanced ready biodegradability tests

*[Please provide a short overall summary of the reported enhanced ready biodegradability test data and conclude on the relevance of the provided information.]*

### BOD5/COD

*[Please provide a short overall summary of the reported BOD5/COD tests and conclude on the relevance of the provided information.]*

### Hydrolysis

*[Please provide a short overall summary of the reported hydrolysis data and conclude on the relevance of the provided information.]*

### Photochemical degradation

*[Please provide a short overall summary of the reported photochemical degradation data and conclude on the relevance of the provided information.]*

### Field investigations and monitoring data (if relevant for the hazard class)

*[Please provide a short overall summary of the reported field investigations and monitoring data and conclude on the relevance of the provided information.]*

### Estimated data on persistence, including read-across

*[Please provide a short overall summary of the reported estimated data, for example ones derived from computational/ QSARs, read-across/grouping, etc. and conclude on the relevance of the provided information. If appropriate, a separate heading for read-across can be created and even be moved in an earlier section if deemed appropriate.]*

### Other convincing scientific evidence

*[Please provide a short overall summary of other reported convincing scientific evidence and conclude on the relevance of the provided information, e.g. information on environmental fate, evidence from treatment facilities, modelling, Long Range Transport potential, decontamination, purification, release reduction, etc.].*

## Bioaccumulation under CLP Annex I, 4.3

*[Please refer to any information that may already be available under a previous section of the CLH report template. Such a reference may be sufficient and no repetition of the same information is needed].*

Table 88. **Summary of relevant information on bioaccumulation under CLP Annex I, 4.3**

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]

[Information on the octanol-water partition can also be presented in the table above.]

### Bioaccumulation in aquatic organisms (pelagic and sediment organisms)

*[Please provide a short overall summary of the reported bioaccumulation testing data in aquatic organisms (e.g. fish bioaccumulation studies) and conclude on the relevance of the provided information.]*

### Bioaccumulation in terrestrial organisms (soil dwelling organisms)

*[Please provide a short overall summary of the reported bioaccumulation testing data in terrestrial organisms and conclude on the relevance of the provided information.]*

### Bioaccumulation in air-breathing organisms (birds, mammals)

*[Please provide a short overall summary of the relevant information for the assessment of bioaccumulation in mammals and other air-breathing organisms, experimental data, modelling, biomonitoring, field data, etc. and conclude on the relevance of the provided information.]*

### Biomagnification in the food chain and/or trophic magnification

*[Please provide a short overall summary of the relevant information for the assessment of biomagnification in the food chain and/or trophic magnification and conclude on the relevance of the provided information.]*

### Levels in biota, including relevant (sub)populations

*[Please provide a short overall summary of the relevant information for the assessment of the levels in biota, including any relevant (sub)populations and conclude on the relevance of the provided information.]*

### Experimental information from human body fluids or tissues (e.g. blood, milk, fat)

*[Please provide a short overall summary of the relevant information for the assessment of any existing experimental information from human body fluids or tissues, e.g. blood, or milk, or fat and conclude on the relevance of the provided information.]*

### Protein binding and binding to membrane lipids

*[Please provide a short overall summary of the relevant information for the assessment of protein binding and binding to membrane lipids (if relevant) and conclude on the relevance of the provided information.]*

### Toxicokinetic assessment

*[Please provide a short overall summary of the relevant information for the assessment of toxicokinetics and conclude on the relevance of the provided information.]*

### Estimated data on bioaccumulation, including read-across

*[Please provide a short overall summary of the reported estimated bioaccumulation (e.g. by use of octanol-water partition coefficient, computed estimates of log Kow or equivalent, by use of other computational techniques/ QSARs, by use of read-across/ grouping) and conclude on the relevance of the provided information. If appropriate, a separate heading for read-across can be created and even be moved in an earlier section if deemed appropriate.]*

### Other convincing scientific evidence

*[Please provide a short overall summary of other reported convincing scientific evidence and conclude on the relevance of the provided information, for example physical-chemical considerations, other reasons for uptake hindrance, binding behaviour, plant enrichment, other bioavailability arguments, benchmarking with known B/vB substances, etc.]*

## Toxicity under CLP Annex I, 4.3

Table 89. **Summary of relevant information on toxicity under CLP Annex I, 4.3**

| **Method/ Study type** | **Test material and purity** | **Results1** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1 Indicate if the results are based on the measured or on the nominal concentration

[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose. For Human Health data, a reference to the respective section in the CLH report may suffice and only some high-level information (e.g. existence of harmonsied classification) can be included].

[Please refer to any information that may already be available under a previous section of the CLH report template (e.g. on aquatic, human health of endocrine disruption hazards). Such a reference may be sufficient and no repetition of the same information is needed].

Environmental data

### Chronic toxicity to fish

*[Please make an overall summary of available chronic toxicity studies to fish and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template]*

### Chronic toxicity to aquatic invertebrates

*[Please make an overall summary of available chronic toxicity studies to aquatic invertebrates and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template]*

### Chronic toxicity to algae or other aquatic plants

*[Please make an overall summary of available chronic toxicity studies to algae or other aquatic plants and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template]*

### Chronic toxicity to other aquatic organisms

*[Please make an overall summary of available chronic toxicity studies to other aquatic organisms – if relevant for C&L - and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template]*

### Chronic toxicity to terrestrial organisms: micro-organisms, invertebrates and plants

*[Please make an overall summary of available chronic toxicity studies to terrestrial organisms: micro-organisms, invertebrates and plants and conclude on the relevance of the provided data.]*

### Chronic toxicity to sediment organisms

*[Please make an overall summary of available chronic toxicity studies to sediment organisms and conclude on the relevance of the provided data.]*

### Reproductive toxicity to birds

*[Please make an overall summary of available chronic toxicity studies to birds and conclude on the relevance of the provided data.]*

### Acute (short-term) toxicity to fish

*[Please make an overall summary of available acute toxicity studies to fish and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template].*

### Acute (short-term) toxicity to aquatic invertebrates

*[Please make an overall summary of available acute toxicity studies to aquatic invertebrates and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template].*

### Acute (short-term) toxicity to algae or other aquatic plants

*[Please make an overall summary of available acute toxicity studies to algae or other aquatic plants and conclude on the relevance of the provided data Link to information that may already be available under a previous section of the CLH report template].*

### Acute (short-term) toxicity to other aquatic organisms

*[Please make an overall summary of available chronic toxicity studies to other aquatic organisms – if relevant for C&L - and conclude on the relevance of the provided data. Link to information that may already be available under a previous section of the CLH report template].*

Endocrine disruption data

### Endocrine disruption for the environment

*[Link to information that may already be available under a previous section of the CLH report template].*

### Endocrine disruption for Human Health

*[Link to information that may already be available under a previous section of the CLH report template].*

Human health data

### Carcinogenicity

*[Link to information that may already be available under a previous section of the CLH report template].*

### Germ cell mutagenicity

*[Link to information that may already be available under a previous section of the CLH report template].*

### Reproductive toxicity

*[Link to information that may already be available under a previous section of the CLH report template].*

### Specific target organ toxicity after repeated exposure

*[Link to information that may already be available under a previous section of the CLH report template].*

### Estimated data on toxicity, including read-across

*[Please provide a short overall summary of the reported estimated data, for example ones derived from computational/ QSARs, read-across/grouping, etc. and conclude on the relevance of the provided information. If appropriate, a separate heading for read-across can be created and even be moved in an earlier section if deemed appropriate.]*

### Other convincing scientific evidence

*[Please provide a short overall summary of other reported convincing scientific evidence and conclude on the relevance of the provided information.]*

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

*[Please make a short summary of the evidence on the persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) properties under CLP Annex I, 4.3. and conclude on the relevance of the provided data.]*

## Comparison with the CLP criteria and conclusion on classification and labelling for PBT/vPvB hazards

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. PBT and vPvB. More details on the assessment approach, e.g. based on parent or ingredient substance, read-across, etc. to be included here, as well as an overall conclusion on the classification. Separate conclusions on P and B and T need to be drawn. These last two sections may also be merged, if appropriate.]*

# Persistent, Mobile and Toxic (PMT) or Very Persistent, Very Mobile (vPvM) properties under CLP Annex I, 4.4

*[Please use the following paragraph (modified as necessary) to reflect the weight-of-evidence you have used: A weight-of-evidence determination according to the provisions of Annex I, Section 4.4.2.4 of CLP Regulation is used to classify the substance as PMT/vPvM. Higher tier information should come first, followed by other supportive elements. All available information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) will be considered together in a weight-of-evidence approach. Information on ingredient substances (constituents/ degradation or transformation products/ impurities/ additives) and any relevant group substance properties belonging to the same category, if relevant, must be recorded under the relevant sub-heading. Further instructions on how to report such information on ingredient substances will be included in the CLP Guidance, currently under development. Please delete all the tables and sub-sections that are not relevant for your dossier. Please amend/delete the suggested table headings below as necessary. Separate tables can be provided for different types of information].*

## Persistence under CLP Annex I, 4.4

*[Link to information that may already be available under a previous section of the CLH report template].*

## Mobility under CLP Annex I, 4.4

Table 90. **Summary of relevant information on mobility under CLP Annex I 4.4**

| **Method/ Study type** | **Test material and purity** | **Results** | **Remarks/Reliability** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*[Please insert/delete rows according to the number of studies. The table is a proposal for data presentation and may be modified from the layout proposed to better fit the purpose.]*

*[For ionisable substances, information on the dissociation constant can also be included in the table above.]*

Experimental data

### Soil adsorption/ desorption studies

*[Please make an overall summary of available experimental studies on the organic carbon- water partition coefficient, usually referring to OECD TG 106 and conclude on the relevance of the provided data]*

### Other adsorption/ desorption studies

*[Please make an overall summary of other relevant information on the organic carbon- water partition coefficient, usually referring to OECD TG 121, sludge and sediment adsorption/desorption studies,* *etc. and conclude on the relevance of the provided data]*

### Experimental information from soil column leaching studies

*[Please make an overall summary of available experimental studies from leaching studies, usually referring to OECD TG 312 and conclude on the relevance of the provided data. Information from soil thin or thick layer chromatography (TLC) experiments, can also be included, here.]*

### Other information from leaching studies (sludge leaching studies)

*[Please make an overall summary of other available information from leaching studies, e.g. from field studies, lysimeter studies, etc. and conclude on the relevance of the provided data]*

### Estimated data on mobility, including read-across

*[Please provide a short overall summary of the reported estimated data, for example ones derived from computational/ QSARs, environmental fate models, read-across/grouping, etc. and conclude on the relevance of the provided information. If appropriate, a separate heading for read-across can be created and even be moved in an earlier section if deemed appropriate.]*

### Water solubility

*[Please make an overall summary of available experimental studies on water solubility, make reference on earlier section, if appropriate]*

### Other convincing scientific evidence (for example, monitoring data)

*[Please make an overall summary of available monitoring data or other relevant information and conclude on the relevance of the provided information.]*

## Toxicity under CLP Annex I, 4.4

*[Link to information that may already be available under a previous section of the CLH report template].*

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

*[Please make a short summary of the evidence on the persistent, mobile and toxic (PMT) and very persistent, very mobile (vPvM) properties under CLP Annex I, 4.4. and conclude on the relevance of the provided data.]*

## Comparison with the CLP criteria and conclusion on classification and labelling for PMT/vPvM hazards

*[Please compare the results with the CLP classification criteria for the hazard class in question, i.e. PMT and vPvM. More details on the assessment approach, e.g. based on parent or ingredient substance, read-across, etc. to be included here, as well as an overall conclusion on the classification. Separate conclusions on P and M and T need to be drawn. These last two sections may also be merged, if appropriate.]*

# EVALUATION OF ADDITIONAL HAZARDS

## Hazardous to the ozone layer

Table 91: 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** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

[Please insert/delete rows according to the number of studies. 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.]*

# References

# Annexes

*[Please add ANNEX I to the CLH report and potential other annexes.]*

1. EATS – estrogenic, androgenic steroidogenic thyroid [↑](#footnote-ref-2)
2. EATS – estrogenic, androgenic steroidogenic thyroid [↑](#footnote-ref-3)