

CLH REPORT FORMAT WITH EXPLANATION

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Substance Name: [Insert substance name]

EC Number: [Insert EC number, if available]

CAS Number: [Insert CAS number, if available]

Index Number: [Insert Annex VI Index number, if available]

Contact details for dossier submitter: [Insert contact details]

Version number: [Insert version number] Date: [Insert date]

EXPLANATORY NOTE

The *Regulation (EC) No. 1272/2008* (CLP Regulation) specifies that Member State competent authorities (MSCAs) as well as manufacturers, importers and downstream users (IND) may submit proposals for harmonised classification and labelling of substances (CLH proposals) to the European Chemicals Agency (ECHA).

The 'Guidance on the preparation of dossiers for harmonised classification and labelling (CLH) under Regulation (EC) No. 1272/2008' ('CLH Guidance') gives detailed guidance on how to prepare a CLH proposal and should be read carefully before starting the preparation of the proposal. The CLH proposal should be submitted as a CLH dossier (CLP Regulation, Annex VI dossier) consisting of a IUCLID 5 technical dossier with a non-confidential CLH report attached.

ECHA is pleased to provide also this complementary CLH report format with explanation for MSCAs and IND in order to facilitate the preparation of the CLH report.

The CLH report is an essential part of the CLH dossier which needs to be prepared carefully. It should be a stand-alone report (see **CLH guidance** for further instructions). The CLH report will be published by the Agency on its website for comments by parties concerned. It will also be used as a basis for the Committee for Risk Assessment (RAC) to prepare its opinion and the background document, which in turn may be used by the Commission for its decision making.

This CLH report format includes all the hazard classes which are meant to be covered depending on the contents of the proposal and the legal framework relevant for the substance. Harmonised classification and labelling of active substances in plant protection products (pesticides; Dir 91/414/EEC, replaced by Regulation (EC) No 1107/2009 from 14 June 2011) and biocidal products (biocides; Dir. 98/8/EC) normally applies to all hazard classes and/or differentiations. Other CLH proposals under the CLP Regulation focus on CMR and respiratory sensitisation hazard classes and/or differentiations (for other hazard classes a justification for action at community level needs to be provided). Therefore this CLH report format provides flexibility in preparing the CLH proposal.

After each heading some explanation is given on what content is meant to be added in that section. However, specific focus should be given to:

Substance identification

• Please provide for each physico-chemical, (eco)-toxicological endpoint and study results all available information on the test substance composition (chemical identity and composition information e.g. source, batch number, purity and impurity profile). For further guidance, please see *CLH Guidance*.

Confidential information

• The CLH report should be a non-confidential report since it will be made available at the ECHA website for public consultation. All the relevant confidential information should instead be included in the appropriate section of the IUCLID 5 dossier and flagged as confidential accordingly. It is also possible to provide a confidential annex attached to the IUCLID Section 13. For further guidance, please see CLH Guidance.

The CLH report format without explanation is meant to be used for preparing the actual CLH report and is available on the ECHA website.

ECHA Secretariat

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Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the IUCLID 5 dossier.]

[Pesticides: This information can be extracted from the IUCLID 5 dossier.]

Table 1: Substance identity

Substance name:	[Insert Substance name]
EC number:	[Insert EC number, if available]
CAS number:	[Insert CAS number, if available]
Annex VI Index number:	[Insert Index number, if available]
Degree of purity:	[Insert value] %
Impurities1:	[Insert, when appropriate]

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¹ [Impurities, additives and minor components are normally not mentioned unless they contribute significantly to the classification of the substance. CLP Regulation, Annex VI, point 1.1.1.4.).]

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation	Directive 67/548/EEC (DSD)
Current entry in Annex VI, CLP Regulation		
Current proposal for consideration by RAC		
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)		

1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or DSD criteria

Table 3: Proposed classification according to the CLP Regulation

[This should include proposed new inclusions into Annex VI, Table 3.1 of the CLP Regulation and/or information about proposed changes or deletions of the current classification.]

[Biocides: This information can be extracted from DocIIA, Section, 1.5.2 'Proposed classification'.]

[Pesticides: This information can be extracted from Volume 1, Level 2, Section 2.1.4 'Classification and labelling' and Annex B.4, 'Proposals for classification and labelling'.]

2.1. Explosives 2.2. Flammable gases 2.3. Flammable aerosols 2.4. Oxidising gases 2.5. Gases under pressure 2.6. Flammable sliquids 2.7. Flammable solids 2.8. Self-reactive substances and mixtures 2.9. Pyrophoric solids 2.10. Pyrophoric solids 2.11. Self-heating substances and mixtures 2.12. Substances and mixtures which in contact with water emit flammable gases 2.13. Oxidising liquids 2.14. Oxidising solids 2.15. Organic peroxides 2.16. Substance and mixtures corrosive to metals 3.1. Acute toxicity - oral Acute toxicity - inhalation 3.2. Skin corrosion / irritation 3.3. Serious eye damage / eye irritation 3.4. Respiratory sensitisation 3.5. Germ cell mutagenicity 3.6. Carcinogenicity 3.7. Reproductive toxicity - ingle caposure - repeated exposure - specific target organ toxicity - specific target organ toxic	CLP	Hazard class	Proposed	Proposed SCLs	Current	Reason for no
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	4.1.					
1) Including specific concentration limits (SCLs) and M-factors		=				

¹⁾ Including specific concentration limits (SCLs) and M-factors 2) Data lacking, inconclusive, or conclusive but not sufficient for classification

<u>Labelling:</u> Signal word:

Hazard statements:

Precautionary statements:

Proposed notes assigned to an entry:

[CLP Regulation, Annex VI, Section 1.1.3.]:

Table 4: Proposed classification according to DSD

[This should include proposed new inclusions into Annex VI, Table 3.2. of the CLP Regulation and/or information about proposed changes or deletions of the current classification.]

[Biocides: This information can be extracted from DocIIA, Section 1.5.2, 'Proposed classification'.]

[Pesticides: This information can be extracted from Volume 1, Level 2, Section 2.1.4 'Classification and labelling' and Annex B.4 'Proposals for classification and labelling'.]

Hazardous property	Proposed classification	Proposed SCLs	Current classification 1)	Reason for no classification ²⁾
Explosiveness				
Oxidising properties				
Flammability				
Other physico-chemical properties [Add rows when relevant]				
Thermal stability				
Acute toxicity				
Acute toxicity – irreversible damage after single exposure				
Repeated dose toxicity				
Irritation / Corrosion				
Sensitisation				
Carcinogenicity				
Mutagenicity – Genetic toxicity				
Toxicity to reproduction – fertility				
Toxicity to reproduction – development				
Toxicity to reproduction – breastfed babies. Effects on or via lactation				
Environment				

¹⁾ Including SCLs

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Indication of danger:
R-phrases:
S-phrases: **Labelling:**

2 BACKGROUND TO THE CLH PROPOSAL

[If considered appropriate, relevant background information to complement the proposal can be included here. For example whether the substance was previously discussed or agreed at TC C&L (Dir. 67/548?EEC) or is coming from Existing Substances Regulation (Regulation 793/93/EC).]

2.1 History of the previous classification and labelling

[Fill in, e.g. previous discussions and/or decisions on classification and labelling that has taken place or other information of help for understanding the proposal.]

2.2 Short summary of the scientific justification for the CLH proposal

[Please give a short summary of the scientific justification for the CLH proposal, and the rationale for classification. This section is intended to include a short version of the scientific justification provided in the summary section of each hazard class considered in this CLH report.]

2.3 Current harmonised classification and labelling

[Biocides: This information can be extracted from Doc IIA, Section 1.5.1 'Current classification'.]

[Pesticides: This information can be extracted from Volume 1, Level 2, Section 2.1.4 'Classification and labelling' and Annex B.4 'Proposals for classification and labelling'.]

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

[This should include the harmonised classification (including SCLs) listed in Annex VI, Table 3.1 of the CLP regulation.] [This information can be extracted from the IUCLID 5.]

2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

[This should include the harmonised classification (including SCLs) listed in Annex VI, Table 3.2 of the CLP regulation.] [This information can be extracted from the IUCLID 5.]

2.4 Current self-classification and labelling

[This should include the harmonised classification and labelling (including SCLs), if available. The reason and justification for no classification should be reported here. It should be stated whether the self-classification is made according to the CLP regulation criteria or according to DSD criteria.] [This information can be found in the IUCLID 5 dossier.]

[Biocides: This information can be found in the Doc IIA, Section 1.5.1, 'Current classification'.]

[Pesticides: This information can be extracted from Volume 1, Level 2, Section 2.1.4 'Classification and labelling' and Annex B.4 'Proposals for classification and labelling'.]

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

2.4.2 Current self-classification and labelling based on DSD criteria

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

[Justifications for all relevant hazard classes, other than CMR and respiratory sensitisation (CLP Regulation, Article 36 and 37), on why there is a need for action at the Community level, should be provided here.]

[Biocides and pesticides: no need for justification (cf. Article 36(3) CLP Regulation)]

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the IUCLID 5 dossier.]

[Pesticides: This information can be extracted from the IUCLID 5 dossier.]

Table 5: Substance identity

EC number:	
EC name:	
CAS number (EC inventory):	
CAS number:	
CAS name:	
IUPAC name:	
CLP Annex VI Index number:	
Molecular formula:	
Molecular weight range:	

Structural formula:

1.2 Composition of the substance

[For each constituent/impurity/additive, fill in the following table (which should be repeated in case of more than one constituent/impurity/additive). The information is particularly important for the main constituent(s) and for the constituents/impurities/additives which influence the outcome of the proposal.]

[This information can be extracted from the IUCLID 5 dossier.]

[Please note that confidential information on specifications should be flagged confidential in IUCLID 5 and/or included in a separate annex attached to the IUCLID 5, Section 13 and flagged confidential.]

[Biocides: This information can be extracted from the IUCLID 5 dossier.]

[In the Draft Assessment Report (DAR), information on impurities and additives is normally in a confidential annex to the report. Concerning biocides, there may be separate confidential annexes at different document levels, or all confidential info is in one document.]

[Pesticides: This information can be extracted from the IUCLID 5 dossier.]

[In the DAR, detailed information on the composition of the substance is normally in the confidential part of the assessment report, Volume 4, Annex C which need to be included as a separate Annex attached to IUCLID 5 and flagged as confidential accordingly.]

Table 6: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks

Current Annex VI entry:

Table 7: Impurities (non-confidential information)

Impurity	Typical concentration	Concentration range	Remarks

Current Annex VI entry:

Table 8: Additives (non-confidential information)

Additive	Function	Typical concentration	Concentration range	Remarks

Current Annex VI entry:

1.2.1 Composition of test material

[Please provide information on the test material used in the different physico-chemical and (eco-)toxicological studies.]

1.3 Physico-chemical properties

[This information can be extracted from the IUCLID 5 dossier.]

[Please indicate whether the values are measured or estimated.]

[Biocides: This information can be extracted from the DocIIIA, Section 3, 'Physical and Chemical Properties of Active Substance' (Summarised in DocIIA, Section 1.3).]

[Pesticides: This information can be extracted from Volume 3, Annex B.2.1 'Physical and chemical properties of the active substance'.]

Table 9: Summary of physico - chemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance 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			
Flash point			
Flammability			
Explosive properties			
Self-ignition temperature			
Oxidising properties			
Granulometry			
Stability in organic solvents and identity of relevant degradation products			
Dissociation constant			
Viscosity			

2 MANUFACTURE AND USES

[The CLH report should also contain a short description of the (main) uses of the substance as this is needed for the purposes of any dissemination concerning this CLH proposal on the ECHA website.]

2.1 Manufacture

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: Does not need to be specified for the CLH proposal. Detailed information on the manufacturing process(es) is provided in the confidential annex of the DAR.]

[Pesticides: Does not need to be specified for the CLH proposal. Detailed information on the manufacturing process(es) is provided in Volume 4, confidential Annex C.].

2.2 <u>Identified uses</u>

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: Short description of use (biocidal product type (PT)) could be indicated. This information can be extracted from the Doc IIA, Section 2.2, 'Field of use envisaged'.]

[Pesticides: Description of the field of use(s) of the pesticides is provided in Volume 1, Level 1, Section 1.5.]

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

[Please fill in this section when relevant for the proposal.]

[This information can be extracted from the IUCLID 5 dossier.] [Repeat the section for every hazard class as appropriate.].

[Biocides: This information can be extracted from the DocIIIA, Section, 3, 'Physical and Chemical Properties of Active Substance'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.2 'Physical and chemical properties'.]

[Whenever results from (robust) study summaries are reported in any sections the following table could be used.]

Table 10: Summary table for relevant physico-chemical studies

Method	Results	Remarks	Reference

3.1 [Insert hazard class when relevant and repeat section if needed]

[This information can be extracted from the IUCLID 5 dossier.]

3.1.1 Summary and discussion of [insert physico-chemical hazard class]

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

3.1.2 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

3.1.3 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4 HUMAN HEALTH HAZARD ASSESSMENT

[Where appropriate, the proposed classification(s) should be included in the summary and discussions sections which will include weight of evidence considerations.]

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 3, 'Human health effects assessment'.]

[Pesticides: This information can be extracted from Volume 3 Annex B.6, 'Toxicology and metabolism' A concise summary is available in Volume 1, Level 2, Section 2.3 'Impact on human and animal health'.]

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.1, 'Toxicokinetics, metabolism and distribution'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.1, 'Absorption, distribution, excretion and metabolism'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.1.1 Non-human information

4.1.2 Human information

4.1.3 Summary and discussion on toxicokinetics

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data.]

4.2 Acute toxicity

Table 11: Summary table of relevant acute toxicity studies

Method	Results	Remarks	Reference

4.2.1 Non-human information

4.2.1.1 Acute toxicity: oral

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 3.2, 'Acute toxicity.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.2.1.2 Acute toxicity: inhalation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 3.2, 'Acute toxicity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.2.1.3 Acute toxicity: dermal

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 3.2, 'Acute toxicity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.2.1.4 Acute toxicity: other routes

[Biocides: This information can be extracted from DocIIA, Section 3.2, 'Acute toxicity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.2.2 Human information

4.2.3 Summary and discussion of acute toxicity

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from DocIIA, Section 3.2, 'Acute toxicity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.2.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.2.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.3 Specific target organ toxicity – single exposure (STOT SE)

4.3.1 Summary and discussion of Specific target organ toxicity – single exposure

[Please summarise the relevant scientific data used for the proposed classification.]

4.3.2 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.3.3 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.4 Irritation

4.4.1 Skin irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

Table 12: Summary table of relevant skin irritation studies

Method	Results	Remarks	Reference

4.4.1.1 Non-human information

4.4.1.2 Human information

4.4.1.3 Summary and discussion of skin irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.4.1.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.4.1.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.4.2 Eye irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

Table 13: Summary table of relevant eye irritation studies

Method	Results	Remarks	Reference

4.4.2.1 Non-human information

4.4.2.2 Human information

4.4.2.3 Summary and discussion of eye irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.4.2.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.4.2.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.4.3 Respiratory tract irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.3, 'Irritation and corrosivity'. Information on humans could be found under section 3.10 'Human data'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.4.3.1 Non-human information

4.4.3.2 Human information

4.4.3.3 Summary and discussion of respiratory tract irritation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.4.3.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.4.3.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.5 Corrosivity

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

Table 14: Summary table of relevant corrosivity studies

Method	Results	Remarks	Reference

4.5.1 Non-human information

4.5.2 Human information

4.5.3 Summary and discussion of corrosivity

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.3, 'Irritation and corrosivity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.5.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.5.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.6 Sensitisation

4.6.1 Skin sensitisation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.4, 'Sensitisation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

Table 15: Summary table of relevant skin sensitisation studies

Method	Results	Remarks	Reference

4.6.1.1 Non-human information

4.6.1.2 Human information

4.6.1.3 Summary and discussion of skin sensitisation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.4, 'Sensitisation'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.6.1.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.6.1.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.6.2 Respiratory sensitisation

[This information can be extracted from the IUCLID 5 dossier.]

[Please indicate whether the endpoint has or has not been reviewed, in addition to indicating whether classification is proposed.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.4, 'Sensitisation'. Information on humans could be found under Section 3.10 'Human data'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.2, 'Acute toxicity including irritancy and skin sensitization'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

Table 16: Summary table of relevant respiratory sensitisation studies

Method	Results	Remarks	Reference

4.6.2.1 Non-human information

4.6.2.2 Human information

4.6.2.3 Summary and discussion of respiratory sensitisation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.4, 'Sensitisation'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.6.2.4 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.6.2.5 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.7 Repeated dose toxicity

Table 17: Summary table of relevant repeated dose toxicity studies

Method	Results	Remarks	Reference

4.7.1 Non-human information

4.7.1.1 Repeated dose toxicity: oral

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.5, 'Repeated dose toxicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section 6.3, 'Short-term toxicity' and B6.5, 'Long-term toxicity and carcinogenicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.7.1.2 Repeated dose toxicity: inhalation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section, 35 'Repeated dose toxicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section 6.3, 'Short-term toxicity' and B6.5, 'Long-term toxicity and carcinogenicity' A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.7.1.3 Repeated dose toxicity: dermal

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, section, 3.5, 'Repeated dose toxicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section 6.3, 'Short-term toxicity' and B6.5, 'Long-term toxicity and carcinogenicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.7.1.4 Repeated dose toxicity: other routes

[This information can be extracted from the IUCLID 5 dossier.]

4.7.1.5 Human information

4.7.1.6 Other relevant information

4.7.1.7 Summary and discussion of repeated dose toxicity

[This information can be extracted from the IUCLID 5 dossier].

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.5, 'Repeated dose toxicity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.7.1.8 Summary and discussion of repeated dose toxicity findings relevant for classification according to DSD

[Please summarise the relevant scientific data used for the proposed classification.]

4.7.1.9 Comparison with criteria of repeated dose toxicity findings relevant for classification according to DSD

[Please compare with the criteria in the DSD.]

4.7.1.10 Conclusions on classification and labelling of repeated dose toxicity findings relevant for classification according to DSD

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.8 Specific target organ toxicity (CLP Regulation) – repeated exposure (STOT RE)

4.8.1 Summary and discussion of repeated dose toxicity findings relevant for classification as STOT RE according to CLP Regulation

[Please summarise the relevant scientific data used for the proposed classification by CLP Regulation.]

4.8.2 Comparison with criteria of repeated dose toxicity findings relevant for classification as STOT RE

[Please compare with the criteria in the CLP Regulation.]

4.8.3 Conclusions on classification and labelling of repeated dose toxicity findings relevant for classification as STOT RE

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.9 Germ cell mutagenicity (Mutagenicity)

[Please indicate whether the endpoint has or has not been reviewed, in addition to indicating whether classification is proposed.]

Table 18: Summary table of relevant in vitro and in vivo mutagenicity studies

Method	Results	Remarks	Reference

4.9.1 Non-human information

4.9.1.1 In vitro data

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.6.1, 'Genotoxicity, In vitro'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section 6.4, 'Genotoxicity, in vitro'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.9.1.2 In vivo data

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, section, 3.6.2, 'Genotoxicity, in vivo'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section 6.4, 'Genotoxicity, in vivo'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.9.2 Human information

[This information can be extracted from the IUCLID 5 dossier.]

4.9.3 Other relevant information

[This information can be extracted from the IUCLID 5 dossier.]

4.9.4 Summary and discussion of mutagenicity

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.6, 'Genotoxicity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.9.5 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.9.6 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.10 Carcinogenicity

[Please indicate whether the endpoint has or has not been reviewed, in addition to indicating whether classification is proposed.]

Table 19: Summary table of relevant carcinogenicity studies

Method	Results	Remarks	Reference

4.10.1 Non-human information

4.10.1.1 Carcinogenicity: oral

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.7, 'Carcinogenicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.5, 'Long-term toxicity and carcinogenicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.10.1.2 Carcinogenicity: inhalation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.7, 'Carcinogenicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.5, 'Long-term toxicity and carcinogenicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.10.1.3 Carcinogenicity: dermal

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.7, 'Carcinogenicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.5, 'Long-term toxicity and carcinogenicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.10.2 Human information

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section, 3.10, 'Human data'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 'Medical data and information'.]

4.10.3 Other relevant information

[This information can be extracted from the IUCLID 5 dossier.]

4.10.4 Summary and discussion of carcinogenicity

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.7, 'Carcinogenicity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.10.5 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.10.6 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.11 Toxicity for reproduction

[Please indicate whether the endpoint has or has not been reviewed, in addition to indicating whether classification is proposed.]

Table 20: Summary table of relevant reproductive toxicity studies

Method	Results	Remarks	Reference

4.11.1 Effects on fertility

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.8.2, 'Fertility'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.6, 'Reproductive tocxicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.11.1.1 Non-human information

4.11.1.2 Human information

4.11.2 Developmental toxicity

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.8.1, 'Teratogenicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.6, 'Reproductive toxicity'. A concise summary is available in Volume 1, Level 2, Section 2.3.]

4.11.2.1 Non-human information

4.11.2.2 Human information

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 3.10, 'Human data'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.6, Section 6.9, 'Medical data and information'.]

4.11.3 Other relevant information

[This information can be extracted from the IUCLID 5 dossier.]

4.11.4 Summary and discussion of reproductive toxicity

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

[Biocides: This information can be extracted from the DocIIA, Section 3.8, 'Reproductive toxicity'.]

[Pesticides: This information can possibly be extracted from Volume 1, Level 2, Section 2.3.]

4.11.5 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.11.6 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

4.12 Other effects

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted, e.g. from the DocIIA, Section 3.9, 'Neurotoxicity'.]

[Pesticides: This information can be extracted from Vol 3, Annex B.6, Section B6.7, 'Neurotoxicity' or B6.8 'Further toxicological studies'.]

4.12.1 Non-human information

4.12.1.1 Neurotoxicity

4.12.1.2 Immunotoxicity

4.12.1.3 Specific investigations: other studies

4.12.1.4 Human information

4.12.2 Summary and discussion

[Please summarise the relevant scientific data used for the proposed classification.]

4.12.3 Comparison with criteria

[Please compare with the criteria in both the CLP Regulation and the DSD.]

4.12.4 Conclusions on classification and labelling

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

5 ENVIRONMENTAL HAZARD ASSESSMENT

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from the DocIIA, Section 4.2.]

[Pesticides: This information can be extracted from Volume 3, Annex B.9, Section 2.6 'Effects on non-target species'. A concise summary is available in Volume 1, Level 2, Section 2.6 'Effects on non-target species'.]

5.1 Degradation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1 'Degradation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B 'Environmental fate and behaviour'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

Table 21: Summary of relevant information on degradation

Method	Results	Remarks	Reference

5.1.1 Stability

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1.2, 'Abiotic degradation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.8.4 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5.]

5.1.2 Biodegradation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1.1, 'Biodegradation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.1.2.1 Biodegradation estimation

[This information can be extracted from the IUCLID 5 dossier.]

5.1.2.2 Screening tests

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1.1 'Biodegradation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.1.2.3 Simulation tests

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1.1 'Biodegradation'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.1.3 Summary and discussion of degradation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

5.2 Environmental distribution

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This Information can be extracted from DocIIA, Section 4.1.1.3 'Distribution'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.1 'Route and rate of degradation in soil', Section B.8.4 'Fate and behaviour in water' and Section B.8.7 "Fate and behaviour in air'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.2.1 Adsorption/Desorption

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1.1.3 'Adsorption/Desorption from soils'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.2.2 Volatilisation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.2.3 Distribution modelling

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment.]

5.3 Aquatic Bioaccumulation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

Table 22: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference

5.3.1 Aquatic bioaccumulation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.3.1.1 Bioaccumulation estimation

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.3.1.2 Measured bioaccumulation data

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.1 'Fate and degradation in the environment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.8, Section B.8.4, 'Fate and behaviour in water'. A concise summary is available in Volume 1, Level 2, Section 2.5 'Fate and behaviour in the environment'.]

5.3.2 Summary and discussion of aquatic bioaccumulation

[This information can be extracted from the IUCLID 5 dossier.]

[Please summarise the relevant scientific data used for the proposed classification.]

5.4 Aquatic toxicity

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.2 'Effects on environmental organisms'.]

[Pesticides: This information can be extracted from Volume 3, Annex B.9, Section B.9.2 'Effects on aquatic organisms'.]

Table 23: Summary of relevant information on aquatic toxicity

Method	Results	Remarks	Reference

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.2.1 'Aquatic compartment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.9.2 'Effects on aquatic organisms'.]

5.4.1.2 Long-term toxicity to fish

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: This information can be extracted from DocIIA, Section 4.2.1. 'Aquatic compartment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.9.2 'Effects on aquatic organisms'.]

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: Information available in DocIIA, Section 4.2.1. 'Aquatic compartment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.9.2 'Effects on aquatic organisms'.]

5.4.2.2 Long-term toxicity to aquatic invertebrates

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: Information available in DocIIA, Section 4.2.1. 'Aquatic compartment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.9.2 'Effects on aquatic organisms'.]

5.4.3 Algae and aquatic plants

[This information can be extracted from the IUCLID 5 dossier.]

[Biocides: Information available in DocIIA, Section 4.2.1 'Aquatic compartment'.]

[Pesticides: This information can be extracted from Volume 3, Annex B, Section B.9.2 'Effects on aquatic organisms'.]

5.4.4 Other aquatic organisms (including sediment)

5.5 Comparison with criteria for environmental hazards (sections 5.1 - 5.4)

[Please compare with the criteria in both the CLP Regulation and the DSD.]

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

[Please give the outcome and rationale for the proposed classification.]

[The scientific justification for the proposed classification should be provided.]

6 OTHER INFORMATION

[It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g. registration dossiers, other published sources) used for the dossier could also be indicated here.]

[If relevant, information can be provided in relation to evaluation of the available data, e.g. whether the tested substances correspond to the substance that is proposed to be classified, or justifications for read-across, etc.]

7 REFERENCES

[All the cited references should be included.]

[Biocides: This information can be extracted from the DocII reference list or from a combined reference list which covers the whole DAR.]

[Pesticides: This information can be extracted from Volume 2, Annex A.]

8 ANNEXES

[Non-confidential information only. Confidential information has to be included in a separate Annex, attached to the corresponding IUCLID 5 Section, and flagged as confidential.]