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ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ANNEX 1 PART 1 TO THE REPORT ON THE PILOT PROJECT ON ASSESSING THE POTENTIAL DEVELOPMENT OF A GLOBAL LIST OF CLASSIFIED CHEMICALS

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Series on Testing & Assessment

No. 246

ANNEX 1 PART 1 TO:

REPORT ON THE PILOT PROJECT ON ASSESSING THE POTENTIAL DEVELOPMENT OF A GLOBAL LIST OF CLASSIFIED CHEMICALS

Joint Pilot Project of the OECD and the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals

This document includes Annex 1 Part 1 of the report.

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris, 2016

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This publication is available electronically, at no charge.

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FOREWORD

This document is Annex 1 Part 1 of the Report on the Pilot Project on Assessing the Potential Development of a Global List of Classified Chemicals. It contains a template for Proposals for Classification and Labelling.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

Proposal for Classification and Labelling (C&L)

Based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

International Chemical Identification:

CAS 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.

TABLE OF CONTENTS

1. IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

International Chemical Identification - **Name(s) in the IUPAC nomenclature or other international chemical name(s)**	*[Examples of available guidance:* *- IUPAC guidance on polymer nomenclature:* http://iupac.org/polyedu/resources/140-Brief-Guide-to-Polymer-Nomenclature-Web-Final-d.pdf *- US EPA guidance on new substances:* http://www.epa.gov/oppt/newchems/pubs/genericnames.pdf *- EU Guidance for identification and naming of substances under REACH and CLP:* 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.]*
CAS number (if available)	
Other identifier(s) (if available)	*[For example EC name, or EC or CIPAC number]*
In case the substance is already included in a classification list - identifier of the entry	*(For example EU Index Number in Annex VI, CLP Regulation)*
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 classification proposal)	*[The minimum and maximum values should be specified.]*

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	The impurity contributes significantly to the classification and labelling [yes/no][1]

[1] *[If yes, please specify how and why the impurity is considered to be relevant for the classification below the table. Within the EU, the name of the impurity should be included in the entry if considered relevant for the classification; in these cases the name of the substance is followed by the text: '(containing ≥ xx % impurity)'. The reference in brackets is then to be considered as a part of the name, and must be included on the label.]*

[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 or not.]

Table 4: 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)	The additive contributes significantly to the classification and labelling (yes/no)

[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 5: Test substances (non-confidential information)

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 C&L is proposed please provide an explanation of why the test substance may be relevant to the proposal, if not explained elsewhere in the report].

2. PROPOSED CLASSIFICATION AND LABELLING

2.1 Proposed classification and labelling according to the GHS criteria (GHS revision number….)

Table 6: Proposed classification and reason for not proposing a classification for a hazard class

GHS chapter ref.	Hazard class or differentiation	Proposed classification - Hazard Class and Category Code(s); Hazard statement Code(s)	Proposed SCL(s) and M-factor(s)	Reason for no proposed classification*
2.1	Explosives			
2.2	Flammable gases			
2.3	Aerosols			
2.4	Oxidising gases			
2.5	Gases under pressure			
2.6	Flammable liquids			
2.7	Flammable solids			
2.8	Self-reactive substances			
2.9	Pyrophoric liquids			
2.10	Pyrophoric solids			
2.11	Self-heating substances			
2.12	Substances which in contact with water emit flammable gases			
2.13	Oxidising liquids			
2.14	Oxidising solids			
2.15	Organic peroxides			
2.16	Corrosive to metals			
2.17	Desensitized explosives			
3.1	Acute toxicity - via oral route			
	- via dermal route			

	- via inhalation route			
3.2	**Skin corrosion/irritation**			
3.3	**Serious eye damage/eye irritation**			
3.4	**Respiratory sensitisation**			
	Skin sensitisation			
3.5	**Germ cell mutagenicity**			
3.6	**Carcinogenicity**			
3.7	**Reproductive toxicity**			
3.8	**Specific target organ toxicity-single exposure**			
3.9	**Specific target organ toxicity-repeated exposure**			
3.10	**Aspiration hazard**			
4.1	**Hazardous to the aquatic environment**			
4.2	**Hazardous to the ozone layer**			

*[*Please select one of the following reasons for not proposing classification for a hazard class:*

- *data lacking;*
- *data inconclusive;*
- *data conclusive but not sufficient for classification;*
- *hazard class not applicable (e.g. if the substance is not in the applicable physical state for the hazard class in question as put on the market or as reasonably expected to be used).]*

Proposed labelling

Pictogram Code(s):

Signal Word Code(s):

Hazard statement Code(s):

Supplemental information *[if relevant]:*

[Please justify the reason for the proposed supplemental information on the label, see 1.4.10.5.4.2 and 1.4.6.3 in GHS]

3. IDENTIFIED USES

[It is recommended but not mandatory that a short description of the (main) uses of the substance is added.]

4. DATA SOURCES

[Please list the data sources and searches that were used to compile this C&L report.]

5. PHYSICOCHEMICAL PROPERTIES

Table 7: 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			
Flash point			
Flammability			
Explosive properties			
Self-ignition temperature			
Oxidising properties			
Granulometry			
Stability in organic solvents and identity of relevant degradation products			
Dissociation constant			
Viscosity			

[add rows, if needed]

6. EVALUATION OF PHYSICAL HAZARDS

6.1 Explosives

Table 8: Summary table of studies on explosive properties

Method	Results	Remarks	Reference

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

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

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.2 Flammable gases

Table 9: Summary table of studies on flammable gases

Method	Results	Remarks	Reference

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

Short summary and overall relevance of the provided information on flammable gases
[Please make a short summary of studies on flammable gases and conclude on the relevance of the provided data.]

Comparison with the GHS criteria
[Please compare the results with the GHS classification criteria for the hazard class in question, i.e. flammable gases.]

Conclusion on classification and labelling for flammable gases
[Please conclude on classification and labelling for flammable gases according to the GHS criteria.]

6.3 Aerosols

Table 10: Summary table of studies on aerosols

Method	Results	Remarks	Reference

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

Short summary and overall relevance of the provided information on aerosols
[Please make a short summary of studies on aerosols and conclude on the relevance of the provided data.]

Comparison with the GHS criteria
[Please compare the results with the GHS classification criteria for the hazard class in question, i.e. aerosols.]

Conclusion on classification and labelling for aerosols
[Please conclude on classification and labelling for oxidising gases according to the GHS criteria.]

6.4 Oxidising gases

Table 11: Summary table of studies on oxidising gases

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.5 Gases under pressure

Table 12: Summary table of studies on gases under pressure

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.6 Flammable liquids

Table 13: Summary table of studies on flammable liquids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.7 Flammable solids

Table 14: Summary table of studies on flammable solids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.8 Self-reactive substances

Table 15: Summary table of studies on self-reactivity

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.9 Pyrophoric liquids

Table 16: Summary table of studies on pyrophoric liquids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.

6.10 Pyrophoric solids

Table 17: Summary table of studies on pyrophoric solids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.11 Self-heating substances

Table 18: Summary table of studies on self-heating substances

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.12 Substances which in contact with water emit flammable gases

Table 19: 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.]

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.13 Oxidising liquids

Table 20: Summary table of studies on oxidising liquids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.14 Oxidising solids

Table 21: Summary table of studies on oxidising solids

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.15 Organic peroxides

Table 22: Summary table of studies on organic peroxides

Method	Results	Remarks	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.16 Corrosive to metals

Table 23: 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.]

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

6.17 De sensitized explosives

Table 9: Summary table of studies on desensitized explosive properties

Method	Results	Remarks	Reference

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

Short summary and overall relevance of the provided information on desensitized explosive properties
[Please make a short summary of studies on desensitized explosive properties and conclude on the relevance of the provided data.]

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

Conclusion on classification and labelling for desensitized explosive properties
[Please conclude on classification and labelling for explosive properties according to the GHS criteria.]

7. TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Table 24: Summary table of toxicokinetic studies

Method	Results	Remarks	Reference

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

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.]

8. EVALUATION OF HEALTH HAZARDS

8.1 Acute toxicity

Acute toxicity - oral route

Table 25a: Summary table of animal studies on acute oral toxicity

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Value LD_{50}	Reference

[Please insert/delete rows according to the number of studies for animal studies on acute oral toxicity.]

Table 25b: Summary table of human data on acute oral toxicity

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 25c: Summary table of other studies relevant for acute oral toxicity

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS classification criteria.]

Acute toxicity - dermal route

Table 26a: Summary table of animal studies on acute dermal toxicity

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Value LD_{50}	Reference

[Please insert/delete rows according to the number of animal studies for acute dermal toxicity.]

Table 26b: Summary table of human data on acute dermal toxicity

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 26c: Summary table of other studies relevant for acute dermal toxicity

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS classification criteria.]

Acute toxicity - inhalation route

Table 27a: Summary table of animal studies on acute inhalation toxicity

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5, form and particle size (MMAD)	Dose levels, duration of exposure	Value LC_{50}	Reference

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

Table 27b: Summary table of human data on acute inhalation toxicity

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 27c: Summary table of other studies relevant for acute inhalation toxicity

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline. Please consider also if the data indicates that the mechanism of toxicity is corrosivity.]

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

8.2 Skin corrosion/irritation

Table 28a: Summary table of animal studies on skin corrosion/irritation

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	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 for skin corrosion/irritation.]

Table 28b: Summary table of human data on skin corrosion/irritation

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 28c: Summary table of other studies relevant for skin corrosion/irritation

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.3 Serious eye damage/eye irritation

Table 29a: Summary table of animal studies on serious eye damage/eye irritation

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	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 for eye damage/eye irritation.]

Table 29b: Summary table of human data on serious eye damage/eye irritation

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 29c: Summary table of other studies relevant for serious eye damage/eye irritation

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.4 Respiratory or skin sensitisation

Respiratory sensitisation

Table 30a: Summary table of animal studies on respiratory sensitisation

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Results	Reference

[Please insert/delete rows according to the number of studies for respiratory sensitisation.]

Table 30b: Summary table of human data on respiratory sensitisation

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 30c: Summary table of other studies relevant for respiratory sensitisation

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

Skin sensitisation

Table 31a: Summary table of animal studies on skin sensitisation

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Results	Reference

[Please insert/delete rows according to the number of studies for skin sensitisation.]

Table 31b: Summary table of human data on skin sensitisation

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 31c: Summary table of other studies relevant for skin sensitisation

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria

[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.5 Germ cell mutagenicity

Table 32a: Summary table of mutagenicity/genotoxicity tests in vitro

Method, test guideline, and deviation(s) if any	Test substance, reference to table 5	Relevant information about the study including rationale for dose selection (as applicable)	Observations	Reference

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

Table 32b: Summary table of mutagenicity/genotoxicity tests in mammalian somatic or germ cells in vivo

Method, test guideline, and deviation(s) if any	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 32c: Summary table of human data relevant for germ cell mutagenicity

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 for the final conclusion on whether the substance is genotoxic or not. If applicable, please consider the significance of any deviations from the test guideline.]

Comparison with the GHS criteria

[Please compare the results with the GHS 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 GHS criteria.]

8.6 Carcinogenicity

Table 33a: Summary table of animal studies on carcinogenicity

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Results	Reference

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

Table 33b: Summary table of human data on carcinogenicity

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 33c: Summary table of other studies relevant for carcinogenicity

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 33d: Are the following factors taken into consideration in the hazard assessment (yes/no)?

Reference	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

Short summary and overall relevance of the provided information on carcinogenicity

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

Comparison with the GHS criteria
[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.7 Reproductive toxicity

Adverse effects on sexual function and fertility

Table 34a: Summary table of animal studies on adverse effects on sexual function and fertility

Method, test guideline, and deviation(s) if any	Species Strain Sex no/group	Test substance, reference to table 5	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 also be summarised in Table 34a.]

Table 34b: Summary table of human data on adverse effects on sexual function and fertility

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 34c: Summary table of other studies relevant for toxicity on sexual function and fertility

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria

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

Adverse effects on development of the offspring

Table 35a: Summary table of animal studies on adverse effects on development of the offspring

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Results	Reference

[Please insert/delete rows according to the number of studies on development of the offspring.]

Table 35b: Summary table of human data on adverse effects on development of the offspring

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 35c: Summary table of other studies relevant for adverse effects on development of the offspring

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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

[Please make a short summary of studies on adverse effects on development of the offspring 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 test guideline.]

Comparison with the GHS criteria

[Please compare the information regarding adverse effects on development of the offspring with the GHS classification criteria for the hazard class in question, i.e. reproductive toxicity.]

Adverse effects on or via lactation

Table 36a: Summary table of animal studies on effects on or via lactation

Method, test guideline, and deviation(s) if any	Species, strain, sex, no/group	Test substance, reference to table 5	Dose levels, duration of exposure	Results	Reference

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

Table 36b: Summary table of human data on effects on or via lactation

Type of data/report	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

Table 36c: Summary table of other studies relevant for effects on or via lactation

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 test guideline.]

Comparison with the GHS criteria

[Please compare the information regarding effects on or via lactation with the GHS 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 GHS criteria, i.e. for adverse effects on sexual function and fertility, and/or on development of the offspring, a substance is allocated to one of two hazard categories. In addition, effects on lactation are allocated in a separate hazard category. 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.]

8.8 Specific target organ toxicity-single exposure (STOT SE)

Table 37a: Summary table of animal studies relevant for STOT SE

Method, test guideline, and deviation(s) if any	Test substance, reference to table 5	Species, strain, sex, no/group	Route of exposure	Dose levels, duration of exposure	Results	Reference

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

Table 37b: Summary table of human data relevant for STOT SE

Type of data/report	Test substance, reference to table 5	Route of exposure	Relevant information about the study (as applicable)	Observations	Reference

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

Table 37c: Summary table of other studies relevant for STOT SE

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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

[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 test guideline.]

Comparison with the GHS criteria

[Please compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.9 Specific target organ toxicity-repeated exposure (STOT RE)

Table 38a: Summary table of animal studies relevant for 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, test guideline, and deviation(s) if any	Test substance, reference to table 5	Species, strain, sex, no/group	Route of exposure	Dose levels, duration of exposure	Results	Reference

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

Table 38b: Summary table of human data relevant for STOT RE

Type of data/report	Test substance, reference to table 5	Route of exposure	Relevant information about the study (as applicable)	Observations	Reference

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

Table 38c: Summary table of other studies relevant for STOT RE

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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

[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 test guideline.]

Table 38d: 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 bw/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.]

Comparison with the GHS criteria
[Please perform a weight of evidence evaluation of all the study results and compare the results with the GHS 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 GHS criteria. Consider also a potential need of setting a specific concentration limit.]

8.10 Aspiration hazard

Table 39: Summary table of evidence for aspiration hazard

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]

9. EVALUATION OF ENVIRONMENTAL HAZARDS

9.1 Acute aquatic hazard

Table 40: Summary of relevant information on acute aquatic toxicity

Method, test guideline, and deviation(s) if any	Species	Test material	Results[1]	Key or Supportive study	Remarks	Reference

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

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 classification - and conclude on the relevance of the provided data.]

9.2 Long-term aquatic hazard

Table 41: Summary of relevant information on chronic aquatic toxicity

Method, test guideline, and deviation(s) if any	Species	Test material	Results	Key or Supportive study	Remarks	Reference

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

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 classification - and conclude on the relevance of the provided data.]

9.3 Bioaccumulation

Table 42: Summary of relevant information on bioaccumulation

Method, test guideline, and deviation(s) if any	Species	Results	Key or Supportive study	Remarks	Reference

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.]

9.4 Rapid degradability of organic substances

Table 43: Summary of relevant information on rapid degradability

Method, test guideline, and deviation(s) if any	Results	Key or Supportive study	Remarks	Reference

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

BOD_5/COD
[Please provide a short overall summary of the reported BOD_5/COD tests 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.]

Aquatic simulation tests
[Please provide a short overall summary of the reported aquatic simulation tests and conclude on the relevance of the provided information.]

Field investigations and monitoring data (if relevant for C&L)
[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.]

Soil and sediment degradation data
[Please provide a short overall summary of the reported soil and sediment degradation data 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.]

9.5 Environmental transformation of metals or inorganic metal compounds

Table 44: Summary of relevant information on rapid environmental transformation

Method, test guideline, and deviation(s) if any	Results	Key or Supportive study	Remarks	Reference

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.]

9.6 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).]

9.7 Comparison with the GHS criteria for environmental hazards

Acute aquatic hazard
[Please compare the information regarding acute toxicity in aquatic organisms with the GHS 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 GHS 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 4.1.1. in Chapter 4.1 of GHS)]***
- ***bioaccumulation with the GHS classification criteria to conclude on potential for bioaccumulation of the substance.***
- ***degradation with the GHS classification criteria to conclude on rapid degradability of the substance.]***

9.8 Conclusion on classification and labelling for environmental 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.]

10. EVALUATION OF ADDITIONAL HAZARDS

10.1 Hazardous to the ozone layer

Table 45: Summary table of data concerning hazardous properties of the substance for the ozone layer

Type of study/data	Test substance, reference to table 5	Relevant information about the study (as applicable)	Observations	Reference

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

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 GHS criteria
[Please compare the results with the GHS 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 GHS criteria.]