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

Series on Testing & Assessment
No. 246

The corresponding annex is available in the following cotes:
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Unclassified
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OECD Environment, Health and Safety Publications

Series on Testing & Assessment

No. 246

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

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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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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FOREWORD

In 2014, the OECD Task Force on Hazard Assessment (TFHA) and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (JM) agreed to provide a coordination role for a pilot classification project upon invitation from the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS). This is a report of the Pilot Project of the OECD and the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals detailing the process of the pilot project and learnings. It also contains a template for Proposals for Classification and Labelling (Annex 1). Accompanying the report are three case study chemicals where non-binding agreement on their classification have been reached.

1. Report on the Proposal for Classification and Labelling (C&L) of Dimethyltin Dichloride ENV/JM/MONO(2016)44, Series on Testing & Assessment No. 247.

2. Report on the Proposal for Classification and Labelling (C&L) of Dicyclopentadiene ENV/JM/MONO(2016)45, Series on Testing & Assessment No. 248.

3. Report on the Proposal for Classification and Labelling (C&L) of Dibutyl Phthalate ENV/JM/MONO(2016)46, Series on Testing & Assessment No. 249.

The results of this pilot project will be submitted to the UNSCEGHS for consideration in their deliberations on the potential development of a global list of classified chemicals.

This document has been prepared by a project team established for the Pilot Project under the OECD's Task Force on Hazard Assessment. It is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

Background

1. In 2014, the OECD Task Force on Hazard Assessment (TFHA) and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (JM) agreed to provide a coordination role for a pilot classification project upon invitation from the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS).

2. These efforts would build upon the experience of OECD's pilot project on classification in the context of its Cooperative Chemicals Assessment Programme. The outcome of the OECD's pilot project are published (OECD, 2014a,b; OECD, 2016).

3. The pilot project objectives were to:

- To define the process for evaluating chemicals which should provide insight into the level of effort needed to create and maintain a global classification list
- To provide insight into the expertise needed to classify chemicals against the various endpoints, the process(es) to be used for evaluating data and making recommendations on a classification, and the process to be used to finalize and update a classification.
- To determine if non-binding agreement on classification and labelling could be reached on the pilot substances

4. It was also agreed that the following data would be tracked about resources used:

- Time reviewing data and preparing the assessment.
- Time spent in classification.
- Time spent in reviewing and responding to comments.
- Time spent in discussions with the working group on the classifications.

Organisation

5. In order to carry out the pilot project, it was agreed that the work would be organised as follows:

- A fixed number of chemicals would be selected by UNSCGHS
- The preparation of the collection of data and the draft C&L assessment for each nominated chemical would fall under the responsibility of the country or entity that nominated the chemical for the UN pilot exercise.
- To classify the chemicals for all relevant endpoints, as this was required by the guiding principles of UNSCEGHS and would give a better understanding of the resources needed.
- Countries and stakeholders would be invited to participate in the pilot exercise.
- The work would be coordinated by the OECD Secretariat.

Selection of Chemicals

6. Potential chemicals to be considered in the pilot were nominated to the UNSCGHS. Three chemicals were selected for the pilot:

- Dimethyltin dichloride, CAS No. 753-73-1 (Nominated by the European Chemicals Agency)
- Dicyclopentadiene, CAS No. 77-73-6 (Nominated by the Russian Federation)
- Di-n-butyl phthalate, CAS No. 84-74-2 (Nominated by the United States)

Process for Preparation of Reports and Review

7. In order to facilitate the pilot process the three countries nominating the chemicals (referred to in this report as 'sponsor' countries) developed a classification and assessment report form. This includes a Classification and Labelling Report and an Annex to the report for more detailed study information. (This template is available as an Annex (Part 1 and Part 2) to this document).

8. The information used for classification was required to be publically available in order to follow the guiding principles agreed by the UNSCGHS for a pilot on a global list (UNSCGHS, 2012).

9. Considering that a considerable amount of data is published only in the form of robust studies, it was also agreed that the data assessments may use robust summaries if the classifier (i) identifies the studies relied upon, (ii) provides sufficient detail about each study so that its reliability can be assessed, and (iii) obtains additional information about the study if requested by a participant in the classification exercise. It was suggested that summaries of data in IUCLID might be useful for classification, but care must be taken to ensure that those summaries provide enough information so that the reliability of the data can be assessed.

10. The steps of the drafting of the classification and labelling reports were as follows:

i) Sponsor countries drafted their respective classification and labelling reports (C&L reports) and associated Annexes.

ii) Draft C&L reports were circulated via an OECD project website to countries and organisations participating in the pilot project and comments on the draft C&L reports were submitted to the OECD using a standard template (Annex 1).

iii) OECD compiled the comments received on the reports and provided them to the sponsors and the participants of the project.

iv) The sponsor countries revised their draft C&L reports based on the comments and provided responses to the comments

v) The updated reports and response to comments were circulated to the experts participating in the pilot project and discussed through web-meetings (WebEx/teleconference)

vi) Outstanding comments and outcomes of the web-meetings were taken into account by the sponsors in updating the reports and a second web-meeting was scheduled, as needed, to complete the review process

Progression of the Pilot Project

11. The following outlines the general timeline it took for drafting, review and revision of reports. More specific information follows on resources utilised.

a) The three pilot chemicals were selected in October 2014 and a workplan was agreed by the UNSCGHS in December 2014.

b) The sponsor countries agreed on an initial reporting format in October 2014, which was refined throughout the drafting process.

c) The sponsor countries completed their draft classification and labelling reports July-August, 2015 and they were provided to reviewers on 2 September 2015 for a 6 week review period.

d) Comments were received from approximately 10 countries and organizations, and the comments were all uploaded to the OECD site by 5 November 2015.

e) The OECD has prepared comments summaries for each chemical. They show that 6 commenters provided a total of 217 discrete comments on the DCPD draft assessment; 7 commenters provided a total of 118 comments on the DBP draft assessment; and 5 commenters provided a total of 38 comments on DMTC.

f) The chemical sponsors updated their reports based on comments received and provided written responses to comments.

i. For DMTC, the sponsor (ECHA) provided a written response to comments and a revised report 15 December 2015, and on 22 January a teleconference call with was held with interested parties. Based on further feedback received on the call the report was revised, and an additional teleconference was held on 7 April at which time the report was agreed. A finalised report was received on 29 April, 2016.

ii. For DCPD, the sponsor (Russia) provided a written response to comments and revised report on 9 March and a teleconference was held 13 April, with interested parties. Based on further feedback received during the call, a revised report was received 13 May and commented on by written procedure. Following the provision and incorporation of these comments a finalised report was received on 4 July, 2016.

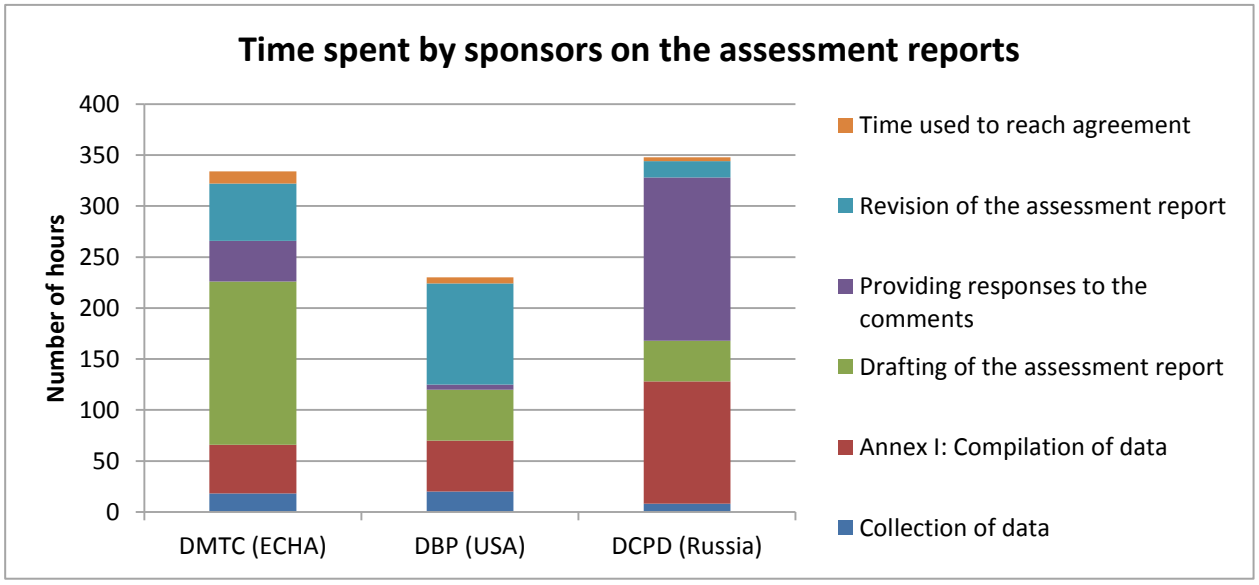
iii. For DBP, the sponsor (United States) provided written responses to the comments and a revised report on 7 March and 26 February respectively, and a teleconference was held 7 April, with interested parties. Based on further feedback received during a revised report was received 26 May and discussed during a teleconference on 8 June. Final comments received on the call were with respect to clarification of a few aspects of the report. A revised version was received on 9 July, 2016.

12. In summary, the timing from when the chemicals were selected to when the classification and labelling reports were finalised, ranged from 18 to 20 months, although this time also included refinement and discussion of the reporting template. The process was all conducted virtually through email correspondence, an on-line platform for sharing documents and through web-based teleconferencing.

Time Tracking for Pilot Project

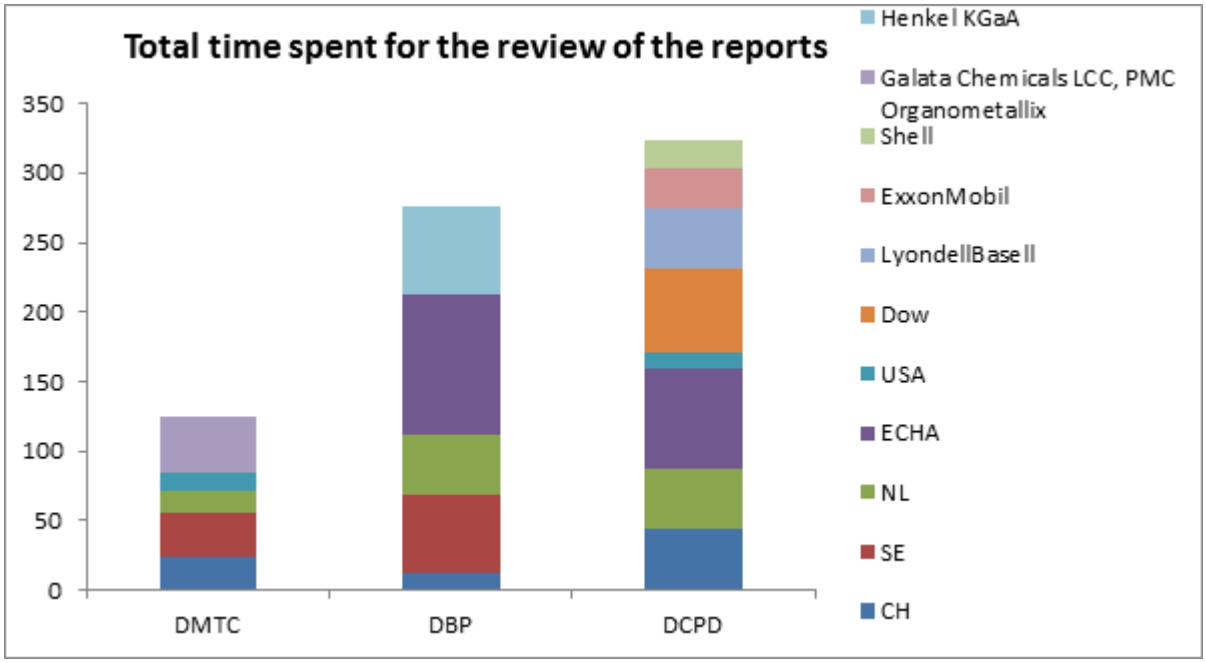
One of the objectives of this pilot exercise is to evaluate the resources needed to prepare the assessments, review them and to come to an agreement. A resource tracking form was filled by the sponsors and participant to the project.

Chemical	Time spent by Dossier submitter	Average time spent by reviewers
DMTC (ECHA)	41.75 days (8h/day)	3.1 days
DBP (USA)	28.5 days	6.9 days
DCPD (Russia)	43.5 days	5 days



13. The time spent in classification was not separately tracked because it was embedded in the drafting of the assessment report.

14. The average total time spent by sponsors is 38 days. They spent in average 21.4 days reviewing data and preparing the assessment and 16.6 days responding to comments and revising the assessment report. For reviewers, the average time spent was 5 days. For each chemical, agreement was reached by written procedure with one or two teleconferences with an average time of 6 hours.



Summary of Learnings from the Pilot Project

Drafting of the Initial Reports - General Comments

15. The drafting of the initial reports took a couple of months longer than anticipated. Contributing factors included large datasets, consistently reporting studies of various types, describing and tabulating the details of studies in the Annex to the report, consideration of the strength and quality of various studies and confidentiality/property rights issues. In the environment section of the template the denotation between "Key or Supportive study" was challenging to differentiate and the "Key and Supportive" column was therefore suggested to be deleted in the summarising tables in the C&L report template. Instead the text could include an evaluation of the use and relevance of the study for classification purposes.

16. In order to summarise information and propose classification and labelling for all GHS endpoints, the sponsors needed to draw from a wide range of expertise within their organisations. This adds to the complexity of drafting the report and underlines that necessity to bring together various technical capabilities to draft a report.

17. Particularly with sponsor authors who were newer to proposing classification and labelling, it was also a learning process as to how much information to provide in the report versus the Annex. Another challenge centred on how to communicate the comparison of the available information against the specific GHS criteria, particularly when there were conflicting data and a weight of evidence determination was needed to be used in order to apply the criteria.

Reviewing, Discussing and Revising of Draft Reports - General Comments

18. Several reviewers noted that it was at times difficult to determine which study, or group of studies, were critical to a classification proposal and commented that more clarity could be sought in this aspect. Related to this, the description of the quality of a study, whether by Klimisch scores, or denoting a study as "Key or Supportive", and the bearing of its quality on its contribution to a classification proposal, was at times lacking in clarity for the reviewer. However, it was noted by one party, that e.g. a given Klimisch score is not reflecting all aspects of the quality of a study. Also, it was suggested that if referred

to, it should be clarified who has assigned the score (as it is the result of a subjective assessment). In addition, this assessment was at times in the Annex of the report while some reviewers thought this would be better placed in the report for all the studies. Nevertheless, it is clear that reliability has to be included in some way in the C&L report and the decision logic and justification of the proposed classification needs to be clearly communicated.

19. In addition to the reliability of the studies, also other study details were sometimes absent or difficult to find. These include for example the guideline used, species, exposure route, and test concentrations. Especially for endpoints for which there are large data collections, a clear presentation of the studies is very helpful.

20. Some reviewers noted that they would have liked to have more information on particular studies that were cited in some cases from secondary sources, and others noted that only primary sources should be used, (which however, may restrict the data considered, as published reports are not always available). Note that in discussions of the UNSCEGHS, it was agreed that unpublished studies could be used in particular circumstances because if a C&L report "could only rely on published reports of data, the universe of substances that could be addressed in a global list was substantially narrowed" (UNSCGHS, 2014).

21. Also, there was a discussion on if previous Classification and Labelling decisions by authorities should be cited and incorporated in a report. If yes, where, and what information should be included? How does this help in deriving the current classification? Is there clarity on what data was used and under what classification system? Initial considerations include that it may provide a source of data and be of value if an independent expert committee has concluded on a classification proposal on the same data base or provided a hazard assessment on some of the same data.

22. A reviewer noted that the review process for DCPD triggered a discussion amongst global industry for proposed revised classification. Therefore the pilot project itself has led to further harmonisation.

23. It was helpful to have a template for comments, so that all comments could be provided to the sponsors to enable them to develop written responses to the comments. Due to the considerable amount of comments for some of the substances, the step of addressing comments took longer than anticipated. Although the development of written responses was time consuming for the sponsors, when completed in a detailed manner it provided reviewers with a clear sense of how their comments were taken on. This expedited dealing with a significant portion of the comments, focusing the web-meetings on key remaining issues.

24. The web-meetings proved necessary and helpful in discussing outstanding issues following the written process. It was through these discussions and dialogue that agreement on a number of more difficult issues was found. Therefore, either web-meetings or face to face meetings are necessary for a successful process.

Technical Learnings

25. There were a number of specific technical issues and learnings that were identified in the pilot process in relation to proposing specific classification and labelling. These are briefly summarized here.

- **Expert judgement -** The application of expert judgement in order to apply the criteria is necessary e.g. in borderline cases between two potential classification outcomes and in case there are contradicting results from the same type of data (e.g. within the same animal species) or

between different type of data (such as animal and human data). This may lead to differences in opinion on what a classification should be. An example of this manifested itself in the context of the DMTC pilot substance for the Reproductive Toxicity (developmental toxicity) - whether a Category 2 vs 1B was warranted. Although consensus was obtained on this issue for this substance, the discussion highlighted the need to bring specialised expertise to the discussion of such cases, and that such cases can lead to a variation in classification outcome.

- **Physical state of the substance -** In the case of DCPD, the physical state of the substance varies in the range of possible handling conditions, depending on its purity and temperature. This led to a discussion on whether a temperature range should be added to a classification. A possibility to use a split "entry" for the solid and liquid (only with regard to flammability) was also mentioned, if considered appropriate. It was agreed that this was impractical, as it would apply for all chemicals, but that the purity could be specified where it impacts the classification. For example, for DCPD a purity-dependent classification for "Flammable Liquids" could be proposed, as commercial grades with purity < 97% are liquids at room temperature (20° C/68° F), and those with higher purity are solids at 20° C/68° F and liquids above 32.2° C/90° F. Also, the temperature of testing, and hence physical state of the substance, can impact endpoints such as aspiration and therefore should be specified when the information is available.

- **Acute Toxicity (oral) -** There was some debate with regard to the selection of species for proposing a classification. Test guidelines typically denote that when selecting a species for acute toxicity testing, the rat is preferred in case of no available data justifying another species; however, when test results from more than one species are available, the general consensus was that the most conservative study should be selected, regardless of species, if there is no further information on species specificity and relevance to humans. This discussion took place in the context of classification proposal for DCPD for Acute Oral Toxicity, where using the mouse study is more conservative.

- **Irritation** –There are differences in reporting and interpretation of the scores for skin and eye irritation. For example, in the case of dibutyl phthalate, the scores for skin and eye irritation in one study were given as PDII scores: 0.54/8 for skin irritation and 0.11/110 for eye irritation. The PDII score is the overall score of a Draize test, calculated as the average of the scores of all animals and time points for erythema and oedema combined. However, classification under GHS is based on the scores of individual animals in combination with information on reversibility and exposure duration. This information cannot be derived from a single PDII score. To ensure consistency and transparency between classifications in the future, there should be consensus on the reporting and interpretation of irritation scores. For example, the result of a skin irritation study of DBP on the ECHA site is given as follows: "After 4 and 24 hours very slight (grade 1) erythema were observed for 2/3 animals. They were completely reversible within after 48 hours". Even where studies are reported through single PDII scores, they can support a weight of evidence approach; however, their limitations need to be accounted for during the classification process.

- **Specific Target Organ Toxicity - Repeated Exposure -** An issue was highlighted regarding what hazard statement to include with a classification for STOT-RE, particularly in terms of level of specificity. Should it be an organ system or the level of a specific organ(s)? This discussion was also supplemented with the sense that since the classification and labelling is used as a communication tool, the hazard statement should also be the most meaningful to the user, including workers and/or general public. This issue arose during the discussion for DMTC. The hazard statement of H372 (nervous system, immune system) for STOT RE 1 was proposed. It was agreed that effects on the thymus were observed; (and according to the dossier submitter,

also effects on the spleen were observed, but to a lesser extent) some participants brought forth the case that the effects on the thymus do not represent a general effect on the competence of the immune system and therefore the hazard statement should be limited to the thymus. A counter to this included that 'immune system' is easier to communicate to the public, in similarity with damage to “fertility” or to "the unborn child”. This issue was noted to be captured as a lesson from the pilot project that could result in different hazard statements being proposed.

- **Environmental hazards -** For the pilot substances there was discussion on how best to present and justify a proposal for environmental hazards classifications. It was suggested that the most practical approach is to conclude for all species at once using the most conservative approach by selecting the most sensitive species, instead of working through each individual species and comparing them to the GHS criteria. The proposed classification will anyhow derive from the most stringent classification across the species.

Other Learnings

26. The strength of the process is very much dependent on the active participation of both sponsors and reviewers, drawing from a breadth of expertise. The initial draft classification and labelling reports improved with the input of reviewers and active discussion amongst participants. Therefore a successful on-going process would need to entail commitment from a larger number of countries and other interested parties to put forward time and resources to both sponsor and actively review substances.

27. The GHS Subcommittee’s guiding principles require opportunities for stakeholders to provide input into the classification process, and industry participants provided comments on and participated in the teleconferences for each of the three pilot chemical classification and labelling reports. However, some stakeholders expressed concerns that they had learned of the exercise by chance, and that a more deliberate means to include to non-member participants be made in future classification exercises.

General Conclusions

28. This pilot project has demonstrated that it is possible to move towards agreement on proposed classification and labelling for substances in some cases as for 3 of 3 pilot substances consensus was reached on draft conclusions in a non-binding environment. However, as on average 38 days was spent drafting and updating reports per sponsor, and an average 5 days spent reviewing the reports per reviewer, this is feasible only with the sustained commitment of time and resources by countries and other interested parties.

REFERENCES

OECD, 2014a. Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31 http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

OECD, 2014b. Annex 3 to the Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31/ANN http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

OECD, 2016. Addendum to the Report of the Pilot Exercise On Classifications For Selected Chemicals. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31/ADD http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

UNSCGHS, 2012. Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its twenty-fourth session held in Geneva from 12 to 14 December 2012, Annex III Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals. Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals. ST/SG/AC.10/C.4/48. http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c4/ST-SG-AC10-C4-48e.pdf

UNSCGHS, 2014. Assessing the potential development of a global list of classified chemicals. UN/SCEGHS/28/INF.22 Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals. Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals. http://www.unece.org/fileadmin/DAM/trans/doc/2014/dgac10c4/UN-SCETDG-28-INF22e.pdf

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English - Or. English

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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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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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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.]

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

15-Nov-2016

English - Or. English

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

ANNEX 1 PART 2 TO THE REPORT ON THE PILOT PROJECT ON ASSESSING THE POTENTIAL DEVELOPMENT OF A GLOBAL LIST OF CLASSIFIED CHEMICALS

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ANNEX 1 PART 2 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 2 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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E-mail: ehscont@oecd.org

FOREWORD

This document is Annex 1 Part 2 of the Report on the Pilot Project on Assessing the Potential Development of a Global List of Classified Chemicals. It contains Annex I to the 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.

SUPPORT ON HOW TO COMPILE ANNEX I TO THE C&L REPORT

The aim of the Annex I is to provide detailed study summaries, transparently and objectively as in the original data source, without subjective interpretations.

The format of the detailed study summary of an individual study is flexible as long as it is clearly reported under the correct hazard class. Under each heading, text in [square brackets] and bullet lists provides guidance on what data to include in each section. This text can be deleted when the Annex I has been finalised.

If read-across to structurally or mechanistically similar substance is used, please provide a justification for using data from this substance and, if known, present the calculations to convert dose/concentration levels from the test substance to the substance for which C&L is proposed. Please provide also a justification for providing non-testing data by any other approaches such as quantitative structure-activity relationships (QSARs) or grouping methods.

TABLE OF CONTENTS

1. PHYSICAL HAZARDS

1.1. Explosives

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

• Pre-treatment of the sample (crushed, sieved, etc.)
• Reference substance
• If alternative apparatus is used, justification needs to be provided as well as correlation to accepted apparatus

Results:

Numerical results (mean value and repeatability) for all tests and controls:
• thermal sensitivity
• mechanical sensitivity
• sensitivity to friction
• Explosive or non-explosive

[Study 2] etc.

1.2. Flammable gases

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

• Description of the apparatus and dimensions
• Test temperature
• Tested concentrations

Results:

• Chemical identity of evolved gas
• Rate of gas evolution (if applicable).
• Indicate lower and upper explosion limits
• Flammability results of test at different test concentrations: non-flammable gas, highly flammable gas?
• Results for the positive control

[Study 2] etc.

1.3. Aerosols

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.4. Oxidising gases

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.5. Gases under pressure

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.6. Flammable liquids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

Results:

- Ignition on contact with air?
- Flammable in contact with water?
- Results for the positive control

[Study 2] etc.

1.7. Flammable solids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

• Indicate if preliminary and/or main test performed
• Moisture content

Results:

• Indicate burning time
• Ignition on contact with air?
• Flammable in contact with water
• Results for a positive control

[Study 2] etc.

1.8. Self-reactive substances

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.9. Pyrophoric liquids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.10. Pyrophoric solids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.11. Self-heating substances

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.12. Substances which in contact with water emit flammable gases

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.13. Oxidising liquids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

• Test material identity, moisture content
• Sample preparation (e.g. grinding, sieving, drying)
• Reference substance (e.g. barium nitrate)
• Combustible substance and drying procedure used
• Preliminary and/or main test used

Results:

• Indicate the results of the spontaneous ignition test
• Indicate the mean pressure rise time for the test substance
• Indicate the mean pressure rise time for the reference substance(s)
• Interpretation of results
• Estimated accuracy of the result (including bias and precision)

[Study 2] etc.

1.14. Oxidising solids

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Material and methods:

• Test material identity, moisture content
• Sample preparation (e.g. grinding, sieving, drying)
• Reference substance (e.g. barium nitrate)
• Combustible substance and drying procedure used
• Preliminary and/or main test used

Results:

• Indicate if in the preliminary test, a vigorous reaction was observed
• Indicate the maximum burning rate for the test mixture
• Indicate the maximum burning rate for the reference mixture
• Interpretation of results
• Estimated accuracy of the result (including bias and precision)

[Study 2] etc.

1.15. Organic peroxides

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.16. Corrosive to metals

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

1.17. Desensitized explosives

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

2. TOXICOKINETICS

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

[Study 2] etc.

3. HEALTH HAZARDS

3.1. Acute toxicity

3.1.1. Acute oral toxicity

Acute oral toxicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. If an estimation method was used, state the equation(s) and/or computer software or other methods applied to calculate the value(s). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties that may be important when assessing acute oral toxicity
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Mode of administration (gavage, in diet, other)
• Duration of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Post exposure observation period
• Control group and treatment
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Statistical methods

Results and reliability:

• Deaths should be those considered to be due to the test substance and should be given in a tabular form showing sex/dose given/no of animals/no of deaths. Information on any other deaths should be provided and explained.
• LD50 or LC50 value with confidence limits, if calculated
• Number of deaths at each dose level
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
  - time of death (provide individual animal time if less than 24 hours afte r dosing).
  - clinical signs: description, severity, reversibility, time of onset and duration at each dose level
  - necropsy findings, including doses affected, severity and number of animals affected
  - potential target organs (if identified in the report)
  - other findings
  - if both sexes tested, results should be compared

[Study 2] etc.

Acute oral toxicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, routine data collection, biological monitoring/personal sampling and published or unpublished industry studies.]

[Study 2] etc.

Acute oral toxicity - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.1.2. Acute dermal toxicity

Acute dermal toxicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide the test material identity, a detailed study summary and results transparently and objectively as in the original data source, without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. If an estimation method was used, state the equation(s) and/or computer software or other methods applied to calculate the value(s). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)

• Batch number
• Physicochemical properties that may be important when assessing acute dermal toxicity
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Mode of administration
• Duration of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Post exposure observation period
• Control group and treatment
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Area covered (e.g. % of body surface)
• Occlusion
• Total volume applied
• Removal of test substance
• Statistical methods

Results and discussion:

• Deaths should be those considered to be due to the test substance and should be given in a tabular form showing sex/dose given/no of animals/no of deaths. Information on any other deaths should be provided and explained.
• LD50 or LC50 value with confidence limits, if calculated
• Number of deaths at each dose level
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
  - time of death (provide individual animal time if less than 24 hours after dosing).
  - clinical signs: description, severity, reversibility, time of onset and duration at each dose level
  - necropsy findings, including doses affected, severity and number of animals affected
  - potential target organs (if identified in the report)
  - other findings
  - if both sexes tested, results should be compared

[Study 2] etc.

Acute dermal toxicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, routine data collection, biological monitoring/personal sampling and published or unpublished industry studies.]

[Study 2] etc.

Acute dermal toxicity - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.1.3. Acute inhalation toxicity

Acute inhalation toxicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. If an estimation method was used, state the

equation(s) and/or computer software or other methods applied to calculate the value(s). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties that may be important when assessing acute inhalation toxicity
• Physical form (gas, vapour, dust, mist)
• Particle size of dust and mist given as mean mass aerodynamic diameter (MMAD) and geometric standard deviation or give other specifications
• Type or preparation of particles (for studies with aerosols)
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Type of inhalation exposure and test conditions (e.g.: exposure apparatus, method of exposure ("whole body", "oro-nasal", or "head only"), exposure data)
• Duration of test/exposure period
• Doses/concentration levels (ppmV (parts per million per volume) for gases, mg/l for vapours, mg/l for dusts and mists) and rationale for dose level selection
• Analytical verification of test atmosphere concentrations
• Post exposure observation period
• Control group and treatment
• Vehicle: identification, concentration and volume used, justification of choice of vehicle
• Statistical methods

Results and discussion:

• Deaths should be those considered to be due to the test substance and should be given in a tabular form showing sex/dose given/no of animals/no of deaths. Information on any other deaths should be provided and explained.
• LD50 or LC50 value with confidence limits if calculated
• Number of deaths at each dose level
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
  - time of death (provide individual animal time if less than 24 hours after dosing).

- clinical signs: description, severity, reversibility, time of onset and duration at each dose level
- necropsy findings, including doses affected, severity and number of animals affected
- potential target organs (if identified in the report)
- other findings
- if both sexes tested, results should be compared

[Study 2] etc.

Acute inhalation toxicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, routine data collection, biological monitoring/personal sampling and published or unpublished industry studies.]

[Study 2] etc.

Acute inhalation toxicity - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.2. Skin corrosion/irritation

Skin corrosion/irritation - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties that could indicate potential for skin irritation/corrosion (e.g. pH value, physical form, oxidising properties)
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Duration of exposure: length of time test material is in contact with animal
• Total dose: amount/concentration of test material applied to skin in mg/ml
• Post exposure observation period
• Control group and treatment
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Time points at which grading/scoring took place, (e.g. 1, 4 24, 48, 72 hours, 14 days, etc.)
• Grading scale: specify/name of the grading/system used

• Preparation of the test site, area covered (e.g. 10% of body surface), shaved or not, abraded or not, pre-treatment of site, patch type: occlusive/semi-occlusive
• Removal of test substance (e.g. water or solvent)
• Statistical methods

Results and discussion:

• Irritant/corrosive response data: cumulative total and percent responders, preferably in tabular form for each individual animal for each observation time period:
  - numerical skin grades at 1, 4, 24, 48 and 72 hours
  - delayed grading scores at 7 to 14 days
• Whether the effects observed were reversible
• Description of all lesions: erythema/oedema findings, other dermal lesions and/or systemic effects.
• Overall irritation score

[Study 2] etc.

Skin corrosion/irritation - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, data from poison information units and accident databases or occupational experience.]

[Study 2] etc.

Skin corrosion/irritation - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.3. Eye damage/eye irritation

Eye damage/eye irritation - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties that could indicate potential for eye damage/eye irritation (e.g. pH value, oxidising properties)
• Is the substance skin corrosive or skin irritant?
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Time points at which grading/scoring took place (e.g. 1 hour, 24, 48, 72 hours, 14 days etc.)
• Name of the scoring method used to score irritation

• Tool used to asses scores: hand-slit lamp, biomicroscope, fluorescein, other
• Duration of test/exposure period
• Doses/concentration levels
• Post exposure observation period
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Removal of test substance (e.g. water or solvent)
• Statistical methods

Results and discussion:

• Irritant/corrosive response data: preferably in tabular form for each individual animal for each observation time period (e.g. 1, 24, 48 and 72 hours)
• Description of serious lesions if observed
• Narrative description of the degree and nature of irritation/corrosion observed
• Description of any non-ocular topical effects observed
• Number of animals affected
• Recovery/irreversibility of the effects (up to 21 days)
• Overall irritation score

[Study 2] etc.

Eye damage/eye irritation - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, data from poison information units and accident databases or occupational experience.]

[Study 2] etc.

Eye damage/eye irritation - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.4. Respiratory sensitisation

Respiratory sensitisation - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[There are currently no formally recognized and validated animal tests for respiratory sensitisation. Please include a description of the test design of relevant tests, if available. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation
• Control group and treatment

Administration/exposure:

• Route of induction and challenge induction
• Induction
  - concentration(s) and volume of test substance
  - induction vehicle (identification, concentration and volume used)
  - note whether more than one dose was given
  - time between dose administration
  - mention any pre-treatment that may have been conducted
• Challenge
  - concentration (if applicable)
  - note whether more than one dose was given
  - vehicle (if applicable)

Results and discussion:

• E.g. measurements of Immunoglobulin E (IgE) and other specific immunological parameters in mice or specific pulmonary responses in guinea pigs.

[Study 2] etc.

Respiratory sensitisation - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type (e.g. lung function tests related to exposure to the substance, in vivo or in vitro immunological tests, bronchial challenge tests), identity of the test substance, test subjects, route of administration, size of the population exposed, extent of exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical history data and case reports, medical surveillance and reporting schemes.]

[Study 2] etc.

Respiratory sensitisation - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.5. Skin sensitisation

Skin sensitisation - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[The Guinea pig maximization test (GPMT), the mouse local lymph node assay (LLNA), Buehler occluded patch test, other. Please state if the study is GLP compliant or not.]

Test substance

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation
• Control group and treatment

Administration/exposure:

• Route of induction and challenge administration:
  - injection/topical
  - with/without occluded patch
  - type of patch used
• Induction:
  - concentration(s) of test substance
  - induction vehicle (identification, concentration and volume used)
  - note whether more than one dose was given
  - the spacing between doses
  - mention any pre-treatment that may have been conducted
• Challenge:
  - concentration (if applicable)
  - note whether more than one dose was given
  - vehicle (if applicable)

Results and discussion:

• Grading system used (traditional tests); for other tests (e.g. LLNA), identify the endpoint to measure effect (e.g. proliferation of lymph nodes)
• Statistical methods
• Conclude whether the test substance is positive, negative or equivocal
• Data should be summarised in tabular form, showing for each animal the skin reactions at each observation point (e.g. number of animals with skin grades of 0, 1, 2, and 3 at each observation time)
• Narrative description of the nature and degree of effects observed
• Any histopathological findings
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
  - whether the substance was a skin irritant at the tested concentrations
  - incidence of skin scores greater than 1 for test and control groups
  - sensitisation ratio (maximisation test)
• Description, severity, time of onset and duration of clinical signs and/or lesions at the site of contact at each dose level
• Results of rechallenge

• For the LLNA study, provide the following additional information:
  - group mean disintegrations/minute and standard deviation
  - stimulation index or fold increase for each group (including positive control) relative to negative control
  - pooled or grouped approach
  - statistical comparisons of groups mean disintegrations per minute (DPMs) compared to controls

[Study 2] etc.

Skin sensitisation - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Provide identity of the test substance, test subjects, route of administration, size of the population exposed, extent of exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical history data and case reports, medical surveillance and reporting schemes.]

[Study 2] etc.

Skin sensitisation - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.6. Germ cell mutagenicity

Germ cell mutagenicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Doses/concentration levels, vehicle, rationale for dose selection
• Vehicle: identification, concentration and volume used, justification for choice of vehicle (if other than water)
• Details on test system and conditions, route of administration, exposure
• Actual doses (mg/kg bw/day) and conversion factor from diet/drinking water test substance concentration (ppm) to the actual dose, if applicable
• Duration of study, frequency of treatment, sampling times and number of samples
• Control groups and treatment
• Positive and negative (vehicle/solvent) control data
• Methods of slide preparation
• Criteria for scoring and number of cells analysed per animal
• Statistical methods

Results and discussion:

• Effect on mitotic index or PCE/NCE (polychromatic erythrocyte/normochromatic erythrocyte) ratio by dose level by sex (if applicable)
• Genotoxic effects (both positive, negative, unconfirmed, dose-response and equivocal)
• Concurrent positive control data
• Statistical results
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
    - mortality at each dose level by sex
    - mutant/aberration/mPCE/polyploidy frequency
    - description, severity, time of onset and duration of clinical signs at each dose level and sex
    - body weight changes by dose and sex

- food/water consumption changes by dose and sex

• Discuss if it can be verified that the test substance reached the general circulation or target tissue, if applicable.

[Study 2] etc.

Germ cell mutagenicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Provide identity of the test substance, test subjects, route of administration, size of the population exposed, extent of exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies and case reports.]

[Study 2] etc.

Germ cell mutagenicity - in vitro data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

Materials and methods:

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. Please state if the study is GLP compliant or not.]

• If no guideline was followed, include a description of the test design:
- number of replicates
- number of doses, justification of dose selection
- positive and negative control groups and treatment
- details on slide preparation
- number of metaphases analyzed
- justification for choice of vehicle

- solubility and stability of the test substance in vehicle if known
- description of follow up repeat study
- criteria for evaluating results (e.g. cell evaluated per dose group, criteria for scoring aberrations)

Test substance

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number

Description of test design:

• Strain or cell type or cell line, target gene if applicable
• Type and composition of metabolic activation system:
  - species and cell type
  - quantity
  - induced or not induced
  - chemicals used for induction
  - co-factors used
• Test concentrations, and reasoning for selection of doses if applicable
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Statistical methods

Results and discussion:

• Justification should be given for choice of tested dose levels (e.g. dose-finding studies)
• Cytotoxic concentrations with and without metabolic activation
• Genotoxic effects (e.g. positive, negative, unconfirmed, dose-response, equivocal) with and without metabolic activation
• Concurrent negative (solvent/vehicle) and positive control data
• Indicate test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they affect the selection of test concentrations or interpretation of the results
• Statistical results
• Additional information that may be needed to adequately assess data for reliability and use, including the following, if available:
  - frequency of reversions/mutations/aberrations, polyploidy
  - mean number of revertant colonies per plate and standard deviation, number of cells with chromosome aberrations and type of chromosome aberrations given separately for each treated and control culture,
  - precipitation concentration if applicable
  - mitotic index

[Study 2] etc.

Germ cell mutagenicity - other data

(e.g. studies on mechanism of action)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.7. Carcinogenicity

Carcinogenicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)

• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Route of administration – oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other
• Duration of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Frequency of treatment
• Control group and treatment
• Post exposure observation period
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Test substance formulation/diet preparation, achieved concentration, stability and homogeneity of the preparation
• Actual doses (mg/kg bw/day) and conversion factor from diet/drinking water test substance concentration (ppm) to the actual dose, if applicable
• Satellite groups and reasons they were added

For inhalation studies:
• Type of inhalation exposure and test conditions (e.g. exposure apparatus)
• Method of exposure (“whole body”, “oro-nasal”, or “head only”), exposure data
• Analytical verification of test atmosphere concentrations
• Particle size (for studies with aerosols, indicate mass median aerodynamic diameter and geometric standard deviation or give other specifications)
• Type or preparation of particles (for studies with aerosols)

For dermal studies:
• Area covered (e.g. % of body surface)
• Occlusion (e.g. semi-occlusive)
• Total volume applied
• Removal of test substance (e.g. water or solvent)

Results and discussion:

Describe the relevant findings (if no effects occurred, explicitly note "No effects").
• Mortality and time to death (indicate number died per sex per dose and time to death)
• Clinical signs

• Body weight gain
• Food/water consumption
• Ophthalmoscopic examination
• Clinical chemistry
• Haematology
• Urinalysis
• Organ weights
• Necropsy findings: nature and severity
• Histopathological findings: nature and severity
• Tumour incidence data by sex, dose and tumour type
• Local or multi-site responses
• Progression of lesions to malignancy
• Gender and/or species-specific responses
• Tumour incidence data by sex, dose and tumour type
• Mode of action (genotoxic, non-genotoxic)
• Toxic response data by sex and dose
• Tumour latency
• Statistical methods and results (unless already described with specific test results above)

[Study 2] etc.

Carcinogenicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Human studies may include epidemiological studies. Please provide a detailed study summary including the study type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

Carcinogenicity - In vitro data

(e.g. *in vitro* germ cell and somatic cell mutagenicity studies, cell transformation assays, gap junction intercellular communication tests)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the study type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

Carcinogenicity - other data

(e.g. studies on mechanism of action)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.8. Reproductive toxicity

Reproductive toxicity - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Route of administration – oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other
• Duration and frequency of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Control group and treatment
• Historical control data if available
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Test substance formulation/diet preparation, achieved concentration, stability and homogeneity of the preparation
• Actual doses (mg/kg bw/day) and conversion factor from diet/drinking water test substance concentration (ppm) to the actual dose, if applicable

If other route of administration than the oral route is chosen, please provide a justification.

<u>For dermal studies:</u>
• Area covered (e.g. % of body surface)
• Occlusion (e.g. semi-occlusive)
• Total volume applied
• Removal of test substance (e.g. water or solvent)

<u>For inhalation studies:</u>
• Type of inhalation exposure and test conditions (e.g.: exposure apparatus)

• Method of exposure ("whole body", "oro-nasal", or "head only"), exposure data
• Analytical verification of test atmosphere concentrations
• Particle size (for studies with aerosols, indicate mass median aerodynamic diameter and geometric standard deviation or give other specifications)
• Type or preparation of particles (for studies with aerosols)

Description of test design:

• Details on mating procedure (M/F ratios per cage, length of cohabitation, proof of pregnancy)
• Premating exposure period for males and females (P and F1)
• dosing schedules and pre and post dosing observation periods for P, F1 and F2, as appropriate
• Standardization of litters (yes/no and if yes, how and when)
• Parameters assessed for P and F1
• Estrous cycle length and pattern, sperm examination, clinical observations performed and frequency
• Parameters assessed for F1 and F2
• Clinical observations performed and frequency, organs examined at necropsy, others (e.g. anogenital distance)
• Post exposure observation period

Results and discussion:

Describe the relevant findings (if no effects occurred, explicitly note "No effects").
• Actual dose received by dose level by sex if known
• Statistical treatment of results, where appropriate
• Provide data on any dose-related observations

<u>For P and F1 adults (per dose):</u>
• Number of animals at the start of the test and matings
• Time of death during the study and whether animals survived to termination
• Body weight data for P and F1 animals selected for mating
• Body weight at sacrifice and absolute and relative organ weight data for the parental animals
• Toxic response data by sex and dose including indices of mating, fertility, gestation, birth, viability and lactation; indicate the numbers used in calculating the indices
• Toxic or other effects on reproduction, offspring, post natal growth
• Clinical observations: description, severity, time of onset and duration
• Haematological and clinical biochemistry findings if available
• Effects on sperm
• Number of P and F1 females cycling normally and cycle length
• Duration of gestation (calculated from day 0 of pregnancy)
• Precoital interval (number of days until mating and number of estrous periods until mating)
• Number of implantations, corpora lutea, litter size
• Number of live births
• Number of pre- and post-implantation loss
• Number of dams with abortions, early deliveries, stillbirths, resorptions and/or dead fetuses
• Data on functional observations
• Necropsy findings
• Histopathological findings: nature and severity
• Body weight change and gravid uterine weight, including optionally, body weight change corrected for gravid uterine weight

• Other organ weight changes if available

For F1 and F2 pups/litters (per dose):
• Mean number of live pups (litter size)
• Sex ratio
• Viability index (pups surviving 4 days/total births)
• Survival index at weaning
• Mean litter or pup weight by sex and with sexes combined
• External, soft tissue and skeletal malformations and other relevant alterations
• Number and percent of fetuses and litters with malformations (including runts) and/or variations as well as description and incidences of malformations and main variations (and/or retardations)
• Data on physical landmarks in pups and other post natal developmental data
• Data on functional observations

[Study 2] etc.

Reproductive toxicity - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Human studies may include epidemiological studies, clinical data and case reports. Please provide a detailed study summary including the study type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

Reproductive toxicity - other data

(e.g. studies on mechanism of action)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]
[Study 2] etc.

3.9. Specific target organ toxicity (single exposure)

Specific target organ toxicity (single exposure) - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. The standard animal studies that may provide information on specific target organ toxicity following single exposure are acute toxicity studies. For respiratory tract irritation there are currently no validated special animal tests, but useful information may be obtained from the single and repeated inhalation toxicity tests. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties (e.g. pH value, physical form, solubility, vapour pressure, particle size)
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex

• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Route of administration – oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other
• Duration and frequency of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Post exposure observation period
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Control group and treatment
• Test substance formulation/diet preparation, achieved concentration by sex and dose level, stability and homogeneity of the preparation
• Actual dose (mg/kg bw) and conversion factor from diet/drinking water test substance concentration (ppm) to the actual dose, if applicable
• Statistical methods

For inhalation studies:
• Type of inhalation exposure and test conditions (e.g.: exposure apparatus,
• Method of exposure ("whole body", "oro-nasal", or "head only"), exposure data
• Analytical verification of test atmosphere concentrations
• Particle size (for studies with aerosols, indicate mass median aerodynamic diameter and geometric standard deviation or give other specifications)
• Type or preparation of particles (for studies with aerosols)

For dermal studies:
• Area covered (e.g. % of body surface)
• Occlusion (e.g. semi-occlusive)
• Total volume applied
• Removal of test substance (e.g. water or solvent)

Results:

Describe the relevant findings and toxic response/effects by sex and dose level (if no effects occurred, explicitly note "No effects").
• Body weight and body weight changes
• Food/water consumption
• Description, severity, time of onset and duration of clinical signs (reversible, irreversible, immediate, delayed)
• Sensory activity, grip strength and motor activity assessments (when available)
• Ophthalmologic findings: incidence and severity
• Haematological findings: incidence and severity
• Clinical biochemistry findings: incidence and severity
• Gross pathology findings: incidence and severity
• Histopathology findings: incidence and severity
• Mortality and time to death (if occurring)

[Study 2] etc.

Specific target organ toxicity (single exposure) - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, available information on the test subjects, route of exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, clinical data and case reports, data from national poisons centres and volunteer studies.]

[Study 2] etc.

Specific target organ toxicity (single exposure) - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.10. Specific target organ toxicity (repeated exposure)

Specific target organ toxicity (repeated exposure) - animal data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design. In addition to standard 28-day, 90-day and 2-year animal studies, other long-term exposure studies such as carcinogenicity, neurotoxicity and reproductive toxicity studies may provide evidence on specific target organ toxicity following repeated exposure. Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
• Physicochemical properties (e.g. pH value, physical form, solubility, vapour pressure, particle size)
[where relevant, reference to table 5 of the C&L report may be sufficient]

Test animals:

• Species/strain/sex
• No. of animals per sex per dose
• Age and weight at the study initiation

Administration/exposure:

• Route of administration – oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other
• Duration and frequency of test/exposure period
• Doses/concentration levels, rationale for dose level selection
• Post exposure observation period
• Vehicle: identification, concentration and volume used, justification of choice of vehicle (if other than water)
• Control group and treatment
• Test substance formulation/diet preparation, achieved concentration by sex and dose level, stability and homogeneity of the preparation
• Actual doses (mg/kg bw/day) and conversion factor from diet/drinking water test substance concentration (ppm) to the actual dose, if applicable
• Satellite groups and reasons they were added
• Statistical methods

For inhalation studies:
• Type of inhalation exposure and test conditions (e.g.: exposure apparatus,
• Method of exposure ("whole body", "oro-nasal", or "head only"), exposure data
• Analytical verification of test atmosphere concentrations
• Particle size (for studies with aerosols, indicate mass median aerodynamic diameter and geometric standard deviation or give other specifications)
• Type or preparation of particles (for studies with aerosols)

For dermal studies:
• Area covered (e.g. of body surface)
• Occlusion (e.g. semi-occlusive)
• Total volume applied
• Removal of test substance (e.g. water or solvent)

Results:

Describe the relevant findings and toxic response/effects by sex and dose level (if no effects occurred, explicitly note "No effects").
• Body weight and body weight changes
• Food/water consumption
• Description, severity, time of onset and duration of clinical signs (reversible, irreversible, immediate, delayed)
• Sensory activity, grip strength and motor activity assessments (when available)
• Ophthalmologic findings: incidence and severity
• Haematological findings: incidence and severity
• Clinical biochemistry findings: incidence and severity
• Gross pathology findings: incidence and severity
• Histopathology findings: incidence and severity
• Terminal organ weights and organ/body weight ratios
• Mortality and time to death (if occurring)

[Study 2] etc.

Specific target organ toxicity (repeated exposure) - human data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, available information on the test subjects, route of exposure and results transparently and objectively as in the original data source without subjective interpretations. Human studies may include epidemiological studies, case reports, and data from medical surveillance schemes and national poisons centres.]

[Study 2] etc.

Specific target organ toxicity (repeated exposure) - other data

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

3.11. Aspiration hazard

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary including the test type, identity of the test substance, test subjects, route of administration, exposure and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

4. ENVIRONMENTAL HAZARDS

4.1. Short-term toxicity to fish

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Acclimation period
• Size and age of fish
• Test conditions (e.g. dissolved oxygen, pH, hardness, type of water, temperature, lighting, test system, solubilising agent, static/ semi-static/ flow-through etc.)
• If semi-static: renewal time, if flow-through: flow rate or renewal time
• Tested doses
• Test duration/total exposure duration
• Test design (e.g. test concentrations throughout the test, number/type of controls, number of replicates, number of animals per replicate and loading, etc.)
• Preliminary test, if conducted

Results:

• Observations in the controls (mortality, number of dead fish, abnormal appearance and behaviour etc.)
• Observations in the test system (mortality, number of dead fish, abnormal appearance and behaviour etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. dissolved oxygen, pH, temperature, etc.)
• LC50 at 24, 48, 72 and 96 hours, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.2. Short-term toxicity to aquatic invertebrates

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Species life stage
• Test conditions (e.g. dissolved oxygen, pH, hardness, type of water, temperature, lighting, test system, solubilising agent, etc.)
• Test duration/total exposure duration
• Acclimation period

• Test design (e.g. test concentrations, number/type of controls, number of replicates, number of animals per vessel, feeding pattern, reference substance used for the organisms sensitivity check, etc.)

Results:

• Observations in the controls (e.g. immobilised organisms etc.)
• Observations in the test system (e.g. immobilised organisms etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. dissolved oxygen, pH, temperature etc.)
• EC50, IC50 or LC50, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.3. Algal growth inhibition tests

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species
• Initial cell concentration

• Test conditions (e.g. temperature, lighting, test medium, pH, test system, solubilising agent, etc.)
• Test duration/total exposure duration
• Test design (e.g. test concentrations, number/type of controls, number of replicates, etc)
• Controls conditions (pH, etc.)

Results:

• Observations in the controls (e.g. increase in biomass, growth rate, etc.)
• Details on the determination of algal biomass (e.g. method for cell counting, cell density, chlorophyll, etc.)
• Determination of growth rates
• Growth curves (e.g. evidence of exponential growth in the controls, growth rate evolution throughout the test in the test vessels, etc.)
• Other effects (e.g. microscopic appearance of algal cells, changes in size, shape or colour, percent mortality of cells, etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (temperature, pH, etc.)
• EC50, EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.4. Lemna sp. growth inhibition test

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)

• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species
• Initial frond number
• Test conditions (e.g. temperature, lighting, test medium, pH, test system, solubilising agent, etc.)
• Test duration/total exposure duration
• Test design (e.g. test concentrations, number/type of controls, number of replicates, etc.)

Results:

• Observations in the controls
• Observations (e.g. frond number, frond area, dry or fresh weight, chlorophyll-a, etc.)
• Determination of growth rates
• Other effects (e.g. frond and root size and appearance, necrosis, chlorosis, gibbosity, loss of buoyancy, etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. pH, light intensity, temperature, etc.)
• EC50, EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.5. Sediment toxicity tests

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.

• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test organisms (e.g. species, age, pre-treatment, etc.)
• Test conditions:
• Sediment – composition of formulated sediment (also pH, organic carbon content, information on possible chemical contamination of sediment components) or origin of natural sediments (also pH, organic carbon content, recommended by C/N ratio and granulometry); conditions of preconditioning of natural sediments; sediment surface area; depth of sediment layer and the ratio of it to the depth of the overlying water
• Water used (e.g. pH, total hardness, ammonium concentration, oxygen content, etc.)
• Solvents or dispersants used for preparation of stock solution
• Food and feeding of test organisms and exposure duration
• Incubation conditions (aeration, temperature, photoperiod and light intensity)
• Method of spiking and equilibrium between water-phase and sediment-phase period
• Data on measured concentrations of test substance in the overlying water, the pore water and the sediment at the start and at the end of the test at the highest concentration and the lower one
• Type of system used (e.g. static)
• Test design (e.g. test concentrations, number/type of controls, number of replicates, number of organisms per replicate, analytical method, etc.)
• Test duration/total exposure duration
• Data to assess the validity of performed test

Results:

• Observations in the controls (e.g. the emergence in the controls at the end of the test, etc.)
• Observations on toxicological effects (e.g. delayed hatching, instar development etc.)

[Study 2] etc.

4.6. OECD TG 218, 219:

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

• Number of emerged male and female midges per vessel and per day
• Number of larvae which failed to emerge as midges per vessel
• Mean individual dry weight of larvae per vessel, and per instar, if appropriate
• Development rate of fully emerged midges per replicate and treatment rate
• % emergence rate per replicate and test concentration

[Study 2] etc.

4.7. OECD TG 225:

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

• Number of worms per replicate at the beginning and end of the test
• Abnormal behaviour if any
• Dry weight of the worms per test chamber
• Total number, and if determined, number of complete and incomplete worms
• Measured test concentrations
• Estimates of the toxic endpoint(s) (e.g. ECx and confidence intervals, NOEC. LOEC) dose- response relationships, description of statistical analysis performed

[Study 2] etc.

4.8. Fish early-life stage (FELS) toxicity test

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Acclimation period
• Size and age of fish
• Test conditions (e.g. dissolved oxygen, pH, hardness, type of water, temperature, lighting, feeding, test system, solubilising agent and its effects, etc.)
• Preliminary test
• Test duration/total exposure duration
• Test design (e.g. test concentrations, number of controls, number of replicates, number of eggs, per replicate and loading, etc.)

Results:

• Observations in the controls (survival of the fertilised eggs, etc.)
• Observations (hatching success and post-hatch survival, abnormal appearance and behaviour, individual weights at the end of the test, etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. dissolved oxygen, pH, hardness, temperature, etc.)
• Expression of results: cumulative mortality; number of healthy fish at the end of the test; time to start of hatching and end of hatching; numbers of larvae hatching each day; number and description of morphological abnormalities; number and description of behavioural effects; length and weight of surviving animals
• EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.9. Fish short term toxicity test on embryo and sac-fry stages

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Acclimation period
• Test conditions (e.g. dissolved oxygen, pH, hardness, type of water, temperature, lighting, test system, solubilising agent, etc.)
• Preliminary test
• Test duration/total exposure duration
• Test design (e.g. test concentrations, number of controls, number of replicates, loading, etc.)

Results

• Observations in the controls (survival of the fertilised eggs, etc.)
• Observations (e.g. hatching success and post-hatch survival, abnormal appearance and behaviour, individual weights at the end of the test, etc.)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. dissolved oxygen, pH, hardness, temperature, etc.)

• Expression of results: cumulative mortality; number of healthy larvae at the end of the test; time to start of hatching and end of hatching; numbers of larvae hatching each day; number and description of morphological abnormalities; number and description of behavioural effects; length and weight of surviving animals
• EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.10. Aquatic Toxicity – Fish, juvenile growth test

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Acclimation period
• Weight of fish at the beginning of the test
• Test conditions (e.g. dissolved oxygen, pH, hardness, type of water, temperature, lighting, feeding, test system8, solubilising agent, etc.)
• Preliminary test
• Test duration/total exposure duration
• Test design (e.g. test concentrations, number of controls, number of replicates, loading, etc.)

Results:

• Observations in the controls: (e.g. mortality, growth rate of control organisms, etc.)
• Observations: growth (weight), any abnormalities (e.g. mortality, appearance, behaviour)
• Monitoring of test concentrations
• Other measurements throughout the test (e.g. dissolved oxygen, pH, hardness, temperature, etc.)
• Expression of results: growth rate, observations on mortality or abnormalities
• EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.11. Chronic toxicity to aquatic invertebrates

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species and origin
• Acclimation period
• Species life stage
• Test conditions (e.g. dissolved oxygen, pH, hardness, TOC, type of water, temperature, lighting, feeding, test system10, solubilising agent, etc.)

• Preliminary test
• Test duration
• Test design (e.g. test concentrations, number of controls, number of replicates, number of animals, etc.)

Results:

• Observations in the controls: (e.g. number of juveniles per parent, presence of living males, ephippia produced, etc.)
• Observations in the test system: number of offspring (daily count), number of dead parents (daily count), any other observed effects (e.g. growth of parents)
• Monitoring of test concentrations
• Other measurements throughout the test (dissolved oxygen, pH, hardness, temperature)
• Expression of results: e.g. total number of living offspring produced per parent animal alive at the end of the test (including control)
• EC10 or NOEC, dose-response relationships, description of statistical analysis performed

[Study 2] etc.

4.12. Chronic toxicity to algae or other aquatic plants

[See short-term toxicity]

4.13. Chronic toxicity to other aquatic organisms

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

4.14. Bioaccumulation test on fish

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]
Detailed study summary and results:
[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Test species, origin and whole body lipid content
• Test conditions: pre-treatment, acclimatisation of test species; durations of uptake and depuration phases; temperature; photoperiod and light intensity; dissolved oxygen concentration; pH (through all the test), hardness, total solids, total organic carbon and salinity of the water; vehicles, solvents or dispersants used (if any); feeding details
• Test design: number and size of test chambers, water volume replacement rate; number of animals per concentration; number of males and females used (together with weight and age); loading rate
• Water quality measurements regime and results
• Substance toxicity to the fish species to be used in the test
• Details on the analytical methods used for determination of the substance in water and test animals

Results:

• Uptake and depuration curves (optional)
• Time to steady state
• Cf (concentration in fish) and Cw (concentration in water) - with standard deviation and range, if appropriate, for all sampling times (Cf expressed in mg/g wet weight of whole body or specified tissues thereof e.g. lipid, and Cw in mg/ml). Cw values for the control series (background should also be reported)
• Steady state BCF value and unit; if available kinetic BCF. BCF should be expressed on tissue type (e.g. whole body, muscle, fillet, liver) and on lipid content, confidence limits and standard deviation (as available) and methods of computation/data analysis for each concentration of test substance used should be reported
• Time of plateau / % of steady-state
• Mortalities and behavioural observations (in test and control)
• Nominal or measured concentrations (monitoring of test concentrations over time in water and test organisms)
• Correction factors and normalisation of results to lipid content
• Correction for growth dilution

[Study 2] etc.

4.15. Bioaccumulation test with other organisms

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.

4.16. Ready biodegradability (screening studies)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)
• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Details on inoculum (nature and sampling site(s), concentration and any pre-conditioning treatment – any adaptation to be mentioned specifically)
• Duration of test
• Details on test conditions (composition of medium, test temperature, pH, CEC (meq/100g), continuous darkness: yes/no, etc.)
• Oxygen conditions (if relevant, the oxygen uptake of the inoculum blank (mg 02/l) after 28 days or oxygen depletion in the inoculum blank after 28 days and the residual concentration of oxygen in the test bottles)
• Initial test substance concentration, vehicle used, pre-acclimatisation
• Information on controls and blank system used
• Details on sampling (frequency, method and sterility)
• Details on analytical method to measure biodegradation
• Identity of reference substance(s) used
• Parameter followed for degradation estimation
• Method of calculating measured concentrations (arithmetic mean, geometric mean, etc.)

Results:

• Degradation % after time, including the result at the end of a 10-day window (does not apply to the MITI method; see the test method for the definition of the 10-day window)
• Degradation results presented preferably with graphs of percentage degradation against time for the test and reference substances, the lag phase, degradation phase, the 10-day window and slope; if no graph then at least indication of the duration of the lag phase, the degradation phase and location of the 10-day window within the test period
• Replicate values of the degradation % of the test chemical at the degradation rate at the plateau, in the end of test, and/or after 10-day window, as appropriate
• Degradation % of the reference compound by day 14 (if relevant also after 7 days)
• Degradation % within 14 days in a toxicity test containing both the test substance and a reference compound
• Specific chemical analytical data, if available
• Any inhibition phenomena or unusual observations or other information affecting the results
• Breakdown products: yes/no, if yes description of breakdown products and the information whether they are transient or stable
• If relevant, inorganic carbon (IC) content of the test substance suspension in the mineral medium at the beginning of the test and total carbon (TC) content;
• If relevant, total C02 evolution in the inoculum blank at the end of the test.

[Study 2] etc.

4.17. BOD5/COD

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

[Study 2] etc.

4.18. Aquatic simulation tests

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

Test substance:

• Indicate if the test material used in the study is equivalent to the substance identified in the C&L dossier.
• EC number (if different from the substance identified in the C&L dossier)
• CAS number (if different from the substance identified in the C&L dossier)

• Degree of purity
• Impurities (or a note that the impurities do not affect the classification)
• Batch number
[where relevant, reference to table 5 of the C&L report may be sufficient]

Materials and methods:

• Details on water/soil/sediment sample (e.g. location and description of sampling site including, if possible, contamination history; if relevant: organic C, clay content and soil texture, Cation Exchange Capacity and pH)
• Duration of test
• Details on test conditions (e.g. test temperature, pH, continuous darkness: yes/no, etc.)
• Oxygen conditions
• Amount of test substance applied, test concentration and reference substance concentration, solubilising agent if relevant
• Information on controls and blank system used
•Details on sampling: (e.g. frequency, method and sterility)
• Repeatability and sensitivity of the analytical methods used including the limit of detection
• (LOD) and the limit of quantification (LOQ), recovery %
• Identity of reference substance(s) used

Results:

• Half-life or DT50, DT75 and DT90 for the test substance and, where appropriate, for major transformation products including confidence limits,
• Averages of the results observed in individual replicates, for example length of lag phase, degradation rate constant and degradation half-life
• The results of the final mass balance check
• Where appropriate, identification, molar concentration and percentage of applied of major transformation products, a proposed pathway of transformation
• Where applicable, an assessment of transformation kinetics for the test substance and characterisation of non-extractable (bound) radioactivity or residues in soil
• Where applicable, degradation % and time interval of degradation of the reference compound

[Study 2] etc.

4.19. Other degradability studies

(e.g. field investigations and monitoring data, inherent and enhanced Ready biodegradability tests, Soil and sediment degradation data, hydrolysis, photochemical degradation, rapid environmental transformation of metals or metal compounds)

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary transparently and objectively as in the original data source without subjective interpretations.]

Test type:

[Test guideline followed and any significant deviations from the guideline if applicable. If no guideline was followed, include a description of the test design (see below). Please state if the study is GLP compliant or not.]

[Study 2] etc.

5. ADDITIONAL HAZARDS

5.1. Hazardous to the ozone layer

[Study 1]

Study reference:

[Authors, title of the article, journal, year, as appropriate]

Detailed study summary and results:

[Please provide a detailed study summary and results transparently and objectively as in the original data source without subjective interpretations.]

[Study 2] etc.