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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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No. 246

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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This publication is available electronically, at no charge.

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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.

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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.