MANUAL FOR INVESTIGATION OF HPV CHEMICALS

CHAPTER 2: SIDS, THE SIDS PLAN AND THE SIDS DOSSIER[1]

Annex 1: Guidance for Completing a SIDS Dossier

In the following form for data submission SIDS elements are clearly stated as such and marked with an asterisk (*). Those elements which are specifically requested for inorganic chemicals are marked with a dagger (†). Where available, templates for Robust Study Summaries are framed.

Form and Guidance for preparing and submitting the SIDS DOSSIER (INCLUDING ROBUST STUDY SUMMARIES)

Cover Page:

SIDS DOSSIER ON THE HPV CHEMICAL

……

CAS No.: …….

Sponsor Country: ……..

Date of submission to OECD: ……..

[1] This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to December 2005.

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Key:

* = Data elements required in the SIDS
† = Data elements specially required for inorganic chemicals
(*) = Data elements to consider based on chemical properties or exposure to environmental compartments

Data Matrix, Chemical Category

Date: (Prepared or Revised)

CAS #						
CHEMICAL NAME						
STUDY		T, E, S, M, H	T, E, S, M, H	T, E, S, M, H	T, E, S, M, H	T, E, S, M, H
PHYSICAL-CHEMICAL DATA						
2.1	Melting Point					
2.2	Boiling Point					
2.3	Density					
2.4	Vapour Pressure					
2.5	Partition Coefficient (log Kow)					
2.6	Water Solubility pH and pKa Values					
2.12	Oxidation:Reduction Potential					
OTHER P/C STUDIES RECEIVED						
ENVIRONMENTAL FATE and PATHWAY						
3.1.A	Photodegradation					
3.1.B	Stability in Water					
3.2	Monitoring Data					
3.3	Transport and Distribution					
3.4	Aerobic Biodegradation					
OTHER ENV FATE STUDIES RECEIVED						
ENVIRONMENTAL TOXICITY						
4.1	Acute Toxicity to Fish					
4.2	Acute Toxicity to Aquatic Invertebrates					
4.3	Toxicity to Aquatic Plants					
4.5.B	Chronic Toxicity to Aquatic Invertebrates					
4.6.A	Toxicity to Terrestrial Plants					
4.6.B	Toxicity to Soil Dwelling Organisms					
OTHER ENV TOXICITY STUDIES RECEIVED						

Data Matrix, Chemical Category - continued

MAMMALIAN TOXICITY						
5.2 A	Acute Oral					
5.2 B	Acute Inhalation					
5.2 C	Acute Dermal					
5.5	Repeated Dose					
5.6	Genetic Toxicity *in vitro* . Gene mutation . Chromosomal aberration					
5.7	Genetic Toxicity *in vivo*					
5.9	Reproductive Toxicity . Fertility . Developmental Toxicity					
	OTHER MAM TOXICITY STUDIES RECEIVED					

T = Test, E = Estimation/Modelling, S = SAR/analogue Data, M = Metabolic Pathway, H = Human Experience

Note: The data matrix above is mainly designed to indicate the availability of data. With some modifications, it can also be used to present actual results. For further guidance see section 3.2 *Guidance on the Development and Use of Chemical Categories in the HPV Chemicals Programme*.

1. GENERAL INFORMATION

1.01 Substance Information

Substance Information contains several **SIDS elements**. The following information should be given in the SIDS Dossier.

A. ***CAS Number** (CAS Number):

B. ***Name** *(OECD name*):

C. **Name** (*IUPAC name*):

D. **†CAS Descriptor** *(where applicable for complex, inorganic chemicals)*:

E. **EINECS Number:**

F. **Molecular Formula:**

G. ***Structural Formula** (*indicate the structural formula in smiles code, if available):*

1.02 OECD Information

The following information should be provided for organisational purposes related to the HPV Chemicals Programme.

A. **Sponsor Country:**

B. **Lead Organisation:**

Name of Lead Organisation (Define lead organisation. Is it a competent authority, industry consortium or company?):

Contact person:
Address:

- Street:
- Postal code:
- Town:
- Country:
- Tel:
- Fax:
- Email:

C. **Name of Responder (Define Responder)**

Name:
Address:

- Street:
- Postal code:
- Town:
- Country:
- Tel:
- Fax:
- Email:

1.03 Details on Chemical Category

If the substance is part of a chemical category, the identity of the substances forming the category should be listed in this section together with the rationale behind the formation of the category.

1.1 General Substance Information

These endpoints are not required SIDS elements. The information allows for a comparison with the test substance which was used in the different tests. This can influence the reliability of certain studies. It is therefore strongly recommended that information on the purity of the produced and marketed substance is made available. In cases were confidentiality issues are involved, the values can be reported in ranges.

A. Type of Substance

Element [ ]; Inorganic [ ]; Natural substance [ ]; Organic [ ]; Organometallic [ ];
Petroleum product [ ]

B. Physical State *(at 20°C and 1.013 hPa)*

Gaseous [ ]; Liquid [ ]; Solid [ ]

C. Purity *(Indicate the percentage by weight/weight)*:

1.2 Impurities

These endpoints are not required SIDS elements. The information allows for a comparison with the test substance which was used in the different tests. This can influence the reliability of certain studies. It is therefore strongly recommended that information on the impurities of the produced and marketed substance is made available. In cases were confidentiality issues are involved, the values can be reported in ranges.. The CAS No., chemical name (IUPAC name is preferable), percentage, and if applicable the EINECS number, should be indicated in this section.

CAS No:

EINECS No:

Chemical Name:

Remarks:

1.3 Additives

These are not required SIDS elements. However, this general information may be useful in assessing potential toxic properties attributable to the primary chemical or its additives. Information on ingredients like stabilising agents, inhibitors and such like should be added here. The CAS No., chemical name (IUPAC name is preferable), percentage, if applicable the EINECS number should be indicated here.

CAS No:

EINECS No:

Name:

Value:

Remarks:

1.4 Synonyms

Synonyms are not required as SIDS elements, but this general information may be applicable to any substance and so may be useful to have.

Some synonyms are:

1.5 *Quantity

Quantity is a **SIDS element**. The following information should be given in the SIDS Dossier.

Information on annual production and import levels (in metric tonnes) should be provided in figures or ranges (e.g. 1,000-5,000, 5,000-10,000 tonnes per year, etc.) as well as the date and country for which those ranges apply. At a minimum the annual production and import volume in the Sponsor country or, for assessments prepared under voluntary industry programmes, the country where the lead company is located must be provided. If information on import volume is provided, these should clearly be distinguished from the production volume. Recent production volume data from public sources or recent published nameplate capacity is acceptable. If such information is restricted for competitive or antitrust reasons, then volumes should be given in ranges.

Further supporting information – if available - on production volumes can also be reported in this section. Information which would be most relevant for the initial assessment would be:

- the OECD and global annual production quantity or an estimation thereof;
- number of producers in the Sponsor country or, for assessments prepared under voluntary industry programmes, in the country where the lead company is located;
- number and production quantities of producers in other countries.

For all data elements reported in this section, the source of information should also be given in the references.

Remarks:

Reference:

1.6 *Use Pattern

Use Pattern is a **SIDS element.** At a minimum, the use pattern in the Sponsor country or, for assessments prepared under voluntary industry programmes, the country where the lead company is located should be described. Whenever made available, the use pattern in other countries should generally also be included. The following information should be given in the SIDS Dossier.

A. General Use Pattern

Data on the use pattern can be given by assigning main, industrial and use categories according to their exposure relevance.

Main categories

The main categories describe the overall exposure potential of the substance. They are: *use in closed systems*, *use resulting in inclusion into or onto a matrix*, *non-dispersive use* and *wide dispersive use*. These main categories are intended to provide a general impression of the relevance of the exposure during the whole life-cycle:

'Use in closed systems'
This main category refers to the stage of production and industrial/professional use. At the stage of production a substance should only be assigned to this category if it remains within a reactor or is transferred from vessel to vessel through closed pipework, including for transport and storage. If necessary, further information on the method of production can be described in section 1.6.C. For the stage of industrial/professional use this main category refers to substances that are stored, transferred, transported and used only in closed systems, e.g. as closed system intermediates, the application of a substance in a transformer or the circulation circuit of refrigerators. Specific guidance is available on the assessment of chemicals used solely as closed system intermediates (see section 2.3.1).

'Use resulting in inclusion into or onto a matrix'
Use consisting of inclusion into or onto matrices means all processes where chemicals are incorporated into products or articles from which they (normally) will not be released into the environment. This is applicable to the stage of formulation, e.g., when a substance is included in the emulsion layer of a photographic film. It also may refer to the stage of processing, e.g., when a paint additive ends up in the finished coating layer.

'Non-dispersive use'
Non-dispersive use refers to chemicals which are used in such a way that only certain groups of workers, with knowledge of the process, come into contact with these chemicals and in such a way that the environment is exposed only through a limited

number of point sources. This means that the use of these chemicals is related to the number (and size) of the emission sources. So, this main category indicates industrial use at a limited number of sites (where emission reduction measures may be common practice).

'Wide dispersive use'
The term wide dispersive use should be used for a wide range of activities particularly when end users come into contact with the products. For the environment this means a large number of small point sources like households or line sources like traffic.

Industrial categories

Industrial categories describe the industrial branch that uses the substance. Examples of industrial categories are: chemical industry, textile industry, personal and domestic use. A list of industrial categories and guidance how to assign these categories is presented in Annex 1a.

Use categories

The use category describes the function of the substance. Examples of use categories are: colouring agents, intermediates, solvents, adhesives, cleaning/washing agents, fertilisers, impregnation agents, surface active, etc. A list of use categories as proposed by IUCLID as well as a list of synonyms for functions according to ChemUSES is included in Annex 1b. The use categories from these lists should be used wherever applicable. In addition to stating the use categories, a more detailed description on the function of the substance during use as well as the mechanisms involved to fulfil this function can be added in the remarks field. For example if a substance is used as a flame retardant in polymers it should be described whether the substance remains freely available in the polymeric matrix or whether it reacts covalently with the polymer. Also if no entry from the list adequately describes the use, a detailed description of the use should be provided.

For each use, it should be specified to which country the information given pertains. Where there are a variety of uses, an estimation of different uses in percentage terms should be given. For all data elements reported in this section, the source of information should also be given in the references.

Type of Use: **Category:**

(a) Main Industrial Use

Remarks:

(b) Main Industrial Use

Remarks:

Reference:

B. Uses In Consumer Products

If the chemical is present in consumer products as marketed, whether intentionally added or present as e.g. a residual monomer content, details should be given of the function, if any, of the chemical in the products (e.g. a surfactant used in detergents, a solvent used in degreasers, etc.), the percentage of the chemical in the product and the physical state of the product as marketed for typical uses by the consumer to the extent that this information is readily available (e.g. paints may be purchased as a liquid and then subsequently spray applied). It should also be described whether the chemical is freely available, or is covalently bound in the product matrix or to other product components from which it (normally) will not be released.

It is acknowledged that some of the information about the function and the percentage of the chemical in the product may be confidential and cannot be provided. While the absence of this information would not affect the acceptability of the SIDS Documents, it might lead to difficulties when making a recommendation regarding its priority for further work.

Function	**Amount present**	**Physical state**
.....	.....	.....

Remarks:

Reference:

C. Methods of manufacture

If relevant, further information on the method of manufacture (or the method of isolation or separation for streams such as refinery streams and for Class 2 indefinite mixtures) can be reported in the remarks field of this section. Especially for substances for which a limited exposure potential during production is claimed, further details to back up this claim can be reported in this section.

Remarks:

Reference:

1.7 *Sources of Exposure

Sources of Exposure is a **SIDS element**. A description of the potential sources of human (consumers, workers and public) or environmental exposure (at a minimum relating to the use in the Sponsor country or, for assessments prepared under voluntary industry programmes, the country where the lead company is located) should be provided in the SIAR.

This section of the SIDS Dossier can be used to report available information on emissions (measured or estimated). Relevant information include fugitive (or diffuse) emissions inside the facility to air, water, and solid waste, as well as fugitive and point source emissions from the facility to the environmental air, water, or land. Available data should be presented by environmental medium and include quantities, type of release (e.g. point source or diffuse), type of estimating (e.g. average or worst case, uncertainties in estimation), and applicable phases of the life cycle of the chemical where release occurs. Available

information on emissions relating to transport between sites and storage at production and use sites should also be reported in this section.

When reporting releases to the environment during production, the production process (as described in section 1.6.C) should be referred to. When reporting releases to the environment during use, the process of use should be described. If applicable, the basis for concluding that the process of use is "closed" should also be described here.

If data are available, provide an indication of measured released quantities expressed in an appropriate form (e.g. geometric mean and standard deviation).

With the provided information on sources of exposure (workers, consumers, environment), it should always be specified whether it is related to a given site or whether it can be considered to be generic for a given use. For the latter case, a justification should be put forward.

For all information reported in this section, a citation should be given in the reference section.

Source:

Media of release:
Quantities per media:

Remarks:

Reference:

1.8 Additional Information

The following information can be included, if readily available, as it will assist assessment of the exposure information to put any identified hazard(s) into context. The following elements are considered useful.

A. Classification and Labelling

If available, information on the classification and labelling system used, existence of specific limit, symbols, R-Phrases and S-Phrases of EC Directive 67/548/EEC and the like, can be indicated.

Classification

Type:
Category of danger:
R-phrases:

Remarks:

Labelling

Type:
Specific limits:

Symbols:
Nota:
R-phrases:
S-phrases:
Text of S-phrases:

Remarks:

B. Occupational Exposure Limits

The type of occupational exposure limit values including short-term exposure limit value can be indicated. If a value does not exist, the hygiene standard of the producer company, if available, can be given (see Item 5.11 also). It should be noted that these values are subject to national/regional differences and potential change over time.

Exposure Limit Value

Type:
Value:

Short Term Exposure Limit Value

Value:
Length of exposure period:.
Frequency:

Remarks:

Reference:

C. Options for Disposal

The mode of disposal (e.g. incineration, release to sewage system or other) for each category and type of use, if appropriate, should be identified. Recycling possibility should also be mentioned.

Remarks:

Reference:

D. Last Literature Search

The date of the last literature search and the chapters covered should be stated. The search strategy and terms should be described.

E. Other Remarks

2. PHYSICAL CHEMICAL DATA

This section includes the reporting requirements for the physical-chemical elements required for a SIDS Dossier, both for SIDS elements and for non-SIDS elements. The latter should be included when this information is available because it may be relevant and applicable to the assessment of the hazard of the chemical. If more than one value is reported, the recommended value should be identified. Where available, templates for Robust Study Summaries have been included.

Tests for physical/chemical properties should be conducted in principle on the pure substance or the substance as defined by the manufacturing process.

Physical-chemical data for any of the SIDS elements, like boiling point and melting point, when taken from reliable references rather than from actual test reports may be accepted. For example, numerical values from standard references like the CRC Handbook of Chemistry may act as a reference to characterise the physical state and basic chemical properties of an HPV chemical. The MedChem database is also a good source of data. It may be appropriate to support physical-chemical data obtained from standard handbooks with a valid QSAR prediction, within the limitations of the QSAR model.

Information on related compounds may also be useful in affirming physical-chemical parameters.

In the OECD review of SIDS data greater scrutiny is frequently given to the reliability of vapour pressure, octanol/water partition coefficients (K_{ow}) and water solubility studies. Such data are more critical to the initial assessment of potential hazards, e.g. bioaccumulation. Critical information such as temperature and methods used, which affects the value of physical-chemical properties, must be provided in all cases for all testing results and, when available, for data acquired from the literature.

2.1 *Melting Point

Melting Point is a **SIDS element**. The relevant Test Guideline for Melting Point is **OECD Test Guideline 102, 'Melting Point/Melting Range'**.

If more than one melting point value is available, the recommended value should be identified (along with a rationale as to why it is most appropriate value) and the mean of at least 2 measurements reported along with the range of accuracy. Melting points should always be stated for substances other than gases (and liquids, whose melting point is lower than approximately 0°C.) Temperature of decomposition is acceptable. For viscous liquids, "pour point" is an acceptable alternative to report.

A Robust Study Summary template is available for Melting Point.

Test Substance

Identity:

Remarks:*(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed: *(include calculated as one of the possible methods)*
GLP: Yes [ ] No[ ]
Year: *(study performed)*

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Melting point value in °C: *(include <0°C as an acceptable answer)*
Decomposition:Yes [ ] *(temperature °C)* No [ ] Ambiguous [ ]
Sublimation: Yes [ ] No [ ] Ambiguous [ ]

Remarks:*(Describe additional information that may be needed to confirm data reliability and relevance)*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last Changed (*for administrative updating*);
Order number for sorting *(administrative field)*:

Remarks; (*Use for any other comments necessary for clarification)*

2.2 *Boiling Point

Boiling point is a **SIDS element**. The relevant Test Guideline for Boiling Point is **OECD Test Guideline 103, 'Boiling Point'.**

If more than one boiling point value is available, the recommended value should be identified and the mean of at least 2 measurements reported along with the range of accuracy as ^{0}C at a given pressure (kPa). Boiling points should always be stated for substances other than gases or solids and liquids which either boil above 300 ^{0}C or decompose before boiling (in which cases estimates based on vapour pressure or the boiling point under reduced pressure are necessary). For substances which have an obviously high boiling point (e.g. some inorganic or organic salts), an estimation could be sufficient. For certain process streams, such as refinery streams or Class 2 mixtures, the data are often best expressed as boiling point ranges. Temperature of decomposition is acceptable.

A Robust Study Summary template is available for Boiling Point.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method:*(include calculated as one of the possible methods)*
GLP: Yes [ ] No[ ]
Year: *(study performed)*

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Boiling point value in °C: *(include >300°C as an acceptable answer)*
Pressure:
Pressure Unit:
Decomposition: Yes [ ] No [ ] Ambiguous [ ]

Remarks: *(Describe additional information that may be needed to adequately assess data for reliability and use)*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks: *(Use for any other comments necessary for clarification.)*

2.3 †Density (Relative Density)

Density (Relative Density) is a **SIDS element only for inorganic chemicals**. The relevant Test Guideline for Density (Relative density) is **OECD Test Guideline 109, 'Density of Liquids and Solids'**. Information on relative density should be provided for organic chemicals, when it is available.

There is no agreed Robust Study Summary template for this endpoint, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.

GLP: Yes [ ] No [ ] ? [ ]

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Type: Bulk density [ ]; Density [ ]; Relative Density [ ]
Value
Temperature (°C)

Remarks

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.4 *Vapour Pressure

Vapour Pressure is a **SIDS element**. The relevant Test Guideline for Vapour Pressure is **OECD Test Guideline 104, 'Vapour Pressure'.**

A value for this parameter should always be provided. If a boiling point cannot be quoted due to decomposition or the melting point is above 360°C, it may not be necessary to conduct the test for vapour pressure. If a melting point is < 360°C but > 200°C, a limit value based on measurement or a recognised calculation method is acceptable. Calculations that indicate that the vapour pressure is probably less than 10^{-5} Pa at 25°C, could preclude the need for testing. For substances which have an obviously low vapour pressure (e.g. some inorganic or organic salts), an estimation could be sufficient. This test is not essential for chemicals with a boiling point of < 30°C**.** The vapour pressure should be determined for at least 3 temperatures in the range of 0 – 50°C, with the mean vapour pressure expressed as Pascal units (N/m^2) at 20 – 25 °C. An experimental value would be preferred, but there may be interpolation or extrapolation where necessary.

A Robust Study Summary template is available for Vapour Pressure.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method:*(include calculated as one of the possible methods)*
GLP: Yes [ ] No[ ]
Year: *(study performed):*

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Vapour Pressure value: *(include < 10^{-5} Pa as an acceptable answer)*
Temperature (^{0}C):
Decomposition: Yes [ ] *(temperature °C)* No [ ] Ambiguous [ ]

Remarks: *(Describe additional information that may be needed to adequately assess data for reliability and use)* ♣.

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks: *(Use for any other comments necessary for clarification.)*

♣ If a transition (change of state, decomposition) is observed, the following information should be noted: nature of the change, temperature at which the change occurs at atmospheric pressure, vapour pressure at 10 and 20 °C below the transition temperature and 10 and 20 °C above this temperature (unless the transition is from solid to gas).

2.5 *Partition Coefficient ($log_{10}K_{ow}$)

Partition Coefficient is a **SIDS element**. The relevant Test Guidelines for Partition Coefficient are **OECD Test Guidelines 107 and 117.**

For **OECD Test Guideline 107, 'Partition Coefficient (n-octanol/water): Shake Flash Method',** the measurement concentrations (12 concentrations are optimal) for each determination of concentrations in n-octanol and in water, under 3 different conditions, should be included in the free text field for Results.

For **OECD Test Guideline 117, 'Partition Coefficient (n-octanol/water), High Performance Liquid Chromatography (HPLC) Method',** the average retention data should be reported as a mean of at least 2 measurements and should be included in the free text field for Results. Details on fitted regression line, calibration methods, etc. should also be reported.

OECD Test Guideline 122, 'Partition Coefficient (n-octanol/water) pH-Metric Method for Ionisable Substances' might also be considered to be relevant for this element.

If more than one value is reported, the recommended value should be identified (along with a rationale as towhy it is the most appropriate value). Even for those substances which are extremely soluble/insoluble in either phase, an attempt should be made to provide a limit value (if necessary based on the individual solubilities in n-octanol and water). If the test cannot be performed, an estimated value for Log K_{ow} should be provided. However it should be noted that estimated values which are higher than 6 are, in general, not reliable.

The following references may be useful for the calculation of Log K_{ow}:

1. Hansch, C. and Leo, A.J. (1979). Substituent Constants for Correlation Analysis in Chemistry and Biology, John Wiley, New York.

2. Lyman, W.J., Reehl, W.J., Rosenblatt, D.H. (ed.) (1983). Handbook of Chemical Property Estimation Methods, McGraw-Hill, New York.

3. Annex to OECD Test Guideline 117, 'Partition Coefficient (n-octanol/water), HPLC Method'.

4. Application of Structure Activity Relationships to the Estimation of Properties Important in Exposure Assessment, OECD Environment Monograph No.67, 1993.

A Robust Study Summary template is available for Partition Coefficient.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *(include calculated as one of the possible methods)*
GLP: Yes [ ] No[ ]
Year: *(study performed)*

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Log K_{ow}:
Temperature (^{0}C):

Remarks: (*Describe additional information that may be needed to adequately assess data for reliability and use. In particular, note if compound is surface active, dissociating, insoluble in water, metal organic, etc…)*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

2.6.1 *Water Solubility (including *Dissociation Constant).

Water Solubility is a **SIDS element**. The relevant Test Guideline for Water Solubility is **OECD Test Guideline 105, 'Water Solubility'.**

A value for this parameter should always be stated, including gases if necessary, excluding substances unstable in water. Determinations should be made at or near 20°C. If solubility/temperature dependence is > 3% per °C, further measurements should be made at 10°C above and below the initially chosen temperature. If the substance is "insoluble" in water, the detection limit of the analytical method should be indicated. Two to five replicates per trial should be used and information on calibration data for the chosen methods and readings for the test solution should be included. Quantitative values are needed but not below 1 ppb (e.g., less than or equal to 1 µg/L).

*** Dissociation Constant**

Dissociation Constant is a **SIDS element.** The relevant Test Guideline is **OECD Test Guideline 112, 'Dissociation Constants in Water'** for determining pH and pKa values.

Where applicable, values for the dissociation constants (pKa) and the conditions under which they were measured (pH) should be provided. Dissociation constants are particularly important for acids, bases and inorganic chemicals and are normally known, calculated or measured. Dissociation constant testing is not required for chemicals that do not possess functional groups capable of dissociation, e.g., hydrocarbons.

An agreed upon Robust Study Summary template is available for Water Solubility including Dissociation Constant.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method:*(include calculated as one of the possible methods)*
GLP: Yes [ ] No[ ]
Year: *(study performed)*

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value (mg/L) at temperature (^{0}C):

pH value and concentration at temperature (^{0}C):
pKa value at 25 ^{0}C:

Remarks: *(Describe additional information that may be needed to adequately assess data for reliability and use).*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

2.6.2 Surface tension

Surface tension is not a **SIDS element**. If information is available, it should be reported whether a substance has surface-active properties, as this would strongly influence the assessment of the environmental fate of the substance. The relevant Test Guideline for surface tension is **OECD Test Guideline 115, 'Surface Tension of Aqueous Solutions'**.

There is no agreed Robust Study Summary template for this endpoint, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used); please indicate whether the plate method, stirrup method or ring method was used]*.

GLP: Yes [ ] No [ ] ? [ ]

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value
Temperature (°C)
Concentration (mg/l)

Remarks

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.7 Flash Point (Liquids)

Where applicable, the Flash Point of the substance should be indicated although this is not a SIDS element. This property is generally more important for liquids. There is no agreed Robust Study Summary template for Flash Point, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: :*[e.g. OECD, other (with the year of publication or updating of the method used)]*..

GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value (°C):
Type of test: Closed cup [ ]; Open cup [ ]; Other [ ]

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.8 Auto Flammability (Solids/Gases)

Where applicable, the Auto Flammability of the substance should be indicated although this is not a SIDS element. This property is generally more important for solids or gases. There is no agreed Robust Study Summary template for Auto Flammability, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value (°C):
Pressure (hPa):

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.9 Flammability

Where applicable, the Flammability of the substance should be indicated although this is not a SIDS element. There is no agreed Robust Study Summary template for Flammability, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Solids: burning time (s)
highly flammable Yes [ ] No [ ]

Gases lower explosion limit (%)
upper explosion limit (%)

Contact with water Spontaneously flammable in air [ ]
Contact with water liberates highly flammable gases [ ]

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.10 Explosive Properties

Where applicable, the Explosive Properties of the substance should be indicated although this is not a SIDS element. There is no agreed Robust Study Summary template for Explosive Properties, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Explosive under influence of a flame [ ];
More sensitive to friction than m-dinitrobenzene [ ];
More sensitive to shock than m-dinitrobenzene [ ];
Not explosive [ ];
Other [ ]

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.11 Oxidising Properties

Where applicable, the Oxidising Properties of the substance should be indicated although this is not a SIDS element. There is no agreed Robust Study Summary template for Oxidising Properties, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Maximum burning rate equal or higher than reference mixture [ ];
Vigorous reaction in preliminary test [ ];
No oxidising properties [ ];
Other [ ]

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.12 †Oxidation-Reduction Potential

Oxidation-Reduction (Redox) Potential is a **SIDS element for inorganic chemicals.** Oxidation-Reduction (Redox) Potential should also be required for organic chemicals when deemed necessary. At present there is no agreed Robust Study Summary template for Oxidation-Reduction Potential, however the minimum information to be reported is outlined below, and a Robust Study Summary should be prepared when the template is agreed.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value (mV):

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

2.13 Additional Information

This section may be used to include other data that may be relevant to the complete initial hazard assessment of the test substance. Details such as fat solubility, particle size distribution and the like, may be supplied. The following information should be reported for each additional data element.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

3. ENVIRONMENTAL FATE AND PATHWAYS

This section contains the reporting requirements for SIDS elements and for non-SIDS elements. The latter should be included when this information is available because it may be relevant to the assessment of the hazard of the chemical. Where available, templates for Robust Study Summaries have been included.

Reporting of studies should give the test method, test conditions (laboratory versus field studies), test results (e.g. percent degradation in specified time period) and references. Information on breakdown products (transient and stable) should be provided when available.

Note*:* Chemical concentration in various biota should be reported under item 3.2. Data on Biological Effects Monitoring including Biomagnification, and Biotransformation and Kinetics are to be reported under item 4.7 and 4.8 respectively, of the SIDS Dossier. Data on concentration in the workplace or indoor environment should be reported under item 5.10, Experience with Human Exposure.

3.1 Stability

A. *Photodegradation

Photodegradation is a **SIDS element**. An OECD Test Guideline for Photodegradation is currently being developed (Phototransformation of Chemicals in Water-Direct and Indirect Photolysis; Draft New Guideline, August 2000)

For photodegradation, an estimation is generally sufficient. Estimation of photodegradability (and hydrolysis) can be based on reference documents, such as:

OECD Environment Monograph No. 61, The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions (OECD / GD (92)172).

An Assessment of Test Methods for Photodegradation of Chemicals in the Environment" (ECETOC Technical Report No.3)

Lyman, W.J, Reehl,W.J., Rosenblatt, D.H. (ed.) (1983). Handbook of Chemical Property Estimation Methods, McGraw-Hill, New York.

Boethling, R.S., Mackay, D. (ed.) (2000). Handbook of Property Estimation Methods for Chemicals. Lewis Publishers, Boca Raton.

A Robust Study Summary template is available for Photodegradation.

Test Substance

Identity**:**

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed:*(include calculated as one of the possible methods)*
Type: *(test type)*
GLP: Yes [ ] No[ ]
Year: *(study performed*
Light source:
Light spectrum (nm):
Relative Intensity based on Intensity of Sunlight:
Spectrum of substance: *(max lambda, max epsilon and epsilon 295)*

Test Conditions; (*Detail and discuss any significant protocol deviations. Detail differences from the guideline followed including the following as appropriate:*

- *Test medium (air, water, soil, other- specify)*
- *Duration*
- *Positive Controls*
- *Negative Controls)*

Results

Concentration of Substance:
Temperature (°C):
Direct photolysis:

- Half-life t ½ *(preferred):*
- Degradation % after:
- Quantum yield:

Indirect photolysis:

- Sensitiser *(type):*
- Concentration of sensitiser:
- Rate Constant:
- Degradation % after:

Breakdown products: Yes [ ] No [ ]. (*If yes, describe breakdown products and whether they were transient or stable in the Remarks field for Results*).

Remarks: (*Describe additional information that may be needed to adequately assess data for reliability and use).*

Conclusions

Remarks: *(with the ability to identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

B. *Stability in Water

Stability in Water is a **SIDS element**. The relevant Test Guideline for Stability in Water is **OECD Test Guideline 111, 'Hydrolysis as a Function of pH'.**

Testing is generally required for hydrolysis. Consideration should be given to the possible use of estimation methods. Where additional testing is required for hydrolysis, consideration should be given to the choice of

test protocol. When possible, the products of hydrolysis should be identified. Testing or estimation should utilise pH 4, 7 and 9 and other pH levels likely to be found in the environment.

A Robust Study Summary template is available for Stability in Water.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed:*(include calculated as one of the possible methods)*
Type *(test type):*
GLP: Yes [ ] No[ ]
Year: *(study performed)*

Test Conditions: (*Detail and discuss any significant protocol deviations. Detail differences from the guideline followed including the following as appropriate:*

- *Duration:*
- *Positive Controls:*
- *Negative Controls:*
- *Analytical procedures:)*

Results *(Describe additional information that may be needed to adequately assess data for reliability and use).*

Nominal:
Measured value (the value with units preferably as mg/L):
Degradation % at a specified pH and temperature °C % after a specified time:

or

Half-life *($t_{(1/2)}$ in days or hours at a specific pH (pH 4, 7, 9, and other) and temperature):*

Breakdown products: Yes [ ] No [ ]. *(If yes, describe breakdown products and whether they were transient or stable in the Remarks field for Results).*

Remarks

Conclusions

Remarks: (*Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

C. Stability In Soil

This is not a SIDS element. However if soil is a source for deposition, available information on the stability in soil of the substance should be indicated. The relevant Test Guidelines for this endpoint are: **OECD Test Guideline 304A, 'Inherent Biodegradability in Soil'** and the draft **OECD Test Guideline 307, 'Aerobic and Anaerobic Transformation in Soil'.**

There is no Robust Study Summary template, however the minimum information to be reported for substances deposited to soil is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent test substance-specific remarks, e.g. purity of substance.)*

Method

Method: [*e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Type: Field trial [ ]; Laboratory [ ]; Other [ ]
Radiolabel: Yes [ ] No [ ] ? [ ]
Concentration:
Soil temperature (°C):
Soil humidity:
Soil classification: (year) DIN19863 [ ]; NF X31-107 [ ]; USDA [ ]; Other [ ]
Content of clay etc.: Clay (%), Silt (%), Sand (%)
Organic Carbon:
Soil pH:

Cation exchange capacity:
Microbial biomass:
Dissipation time: (DT 50); (DT 90)
Dissipation : (% after _ time)

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

3.2 Monitoring Data (Environment)

Although Monitoring Data (Environment) is no longer a SIDS element, an overview of available monitoring data in the environment with specifications of conditions should be presented. Concentrations in various biota should be reported and ranges given by media type rather than having all data reported individually. Appropriate references should be added to the full data set.

However, biological effects monitoring (biomagnification, biotransformation, are to be reported in Item 3.5. and 3.7. Data on concentration in the workplace or indoor environment should be reported in Item 5.10.

There is no agreed Robust Study Summary template for Monitoring Data (Environment), however the minimum information to be reported is outlined below.

Test Substance

Identity :

Remarks: *(Use for any pertinent test substance-specific remarks, e.g purity of substance.)*

Method

Type of Measurement: Background [ ]; At contaminated site [ ]; Other [ ]
Media: Air [ ]; Biota [ ]; Food [ ]; Ground water [ ]; Sediment [ ]; Soil [ ]; Surface water [ ]; Drinking water [ ]; Other [ ]

Remarks:

Results

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

3.3 *Transport and Distribution

Transport and Distribution Between Environmental Compartments including Distribution Pathways is a **SIDS element**. Information on transport and distribution, as may occur for example during the chemical life cycle, should indicate whether the calculation is on a global basis or is site-specific, and whether it is based on laboratory measurements or field observations. Important environmental fate pathways based on calculations using simple models should be described.

3.3.1 Transport between environmental compartments

Potential chemical partitioning and distribution in the environment can be calculated using computer models. Three such models are described by Mackay *et al*. (1996) and are referred to as equilibrium criterion (EQC) models:

Level I = steady-state, equilibrium, without degradation and advection
Level II = steady-state, equilibrium, with degradation and advection
Level III = steady state, non-equilibrium, with degradation, advection, and inter-media transfer

In particular, calculation of potential chemical distribution between environmental compartments using the Level I model should be provided.

The level III model can be used in two different ways:

- If the releases of a substance to different compartments in a country or a region are known, the model can be used to estimate the resulting concentrations of the substance in each compartment. Within the refocused HPV Chemicals Programme, these estimations are not required.
- The partitioning of a substance between the different compartments depending on the compartment to which the substance is released can be estimated. A fictive amount of the substance can be added alternatively to air, soil and water, and the resulting percentages partitioning to the other compartments can be obtained. When this approach is chosen, the resulting concentrations in the different compartments are fictitious and should not be reported. Only the relative distribution to the different compartments is relevant.

While a level I estimation is sufficient to fulfil the SIDS element, it is recommended to always perform a level III calculation, as it gives a better indication of the environmental fate of the substance.

A Robust Study Summary template is available for Transport between Environmental Compartments.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Type *(fugacity model level I, II or III)*:

Remarks: (*Detail the model used (title, version and date) and the input parameters (physical chemical properties, sizes of the environmental compartments, intermedia partitioning coefficients, degradation rates, etc.) as necessary).*

Results

- Media:
- Estimated Distribution and Media Concentration (levels II/III):

(List the resulting relative distribution (%) in each environmental compartment and if relevant the resulting concentrations in the different compartments (levels II/III only).

Remarks: *(Describe additional information that may be needed to adequately assess data for reliability and use including the following if available:*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

3.3.2 Distribution

Available data on partitioning coefficients between different media should be reported here, e.g. adsorption/ desorption in soil or sediment, Henry's law constant etc.

For adsorption/desorption to soil, the conditions under which it was measured should be indicated although this is not a SIDS element. The relevant Test Guideline for Adsorption/Desorption to Soil is **OECD Test Guideline 106, 'Adsorption-Desorption Using a Batch Equilibrium Method',** or the screening method **OECD Test Guideline 121, 'Estimation of the Adsorption Coefficient (Koc) on soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)**'.

This property is particularly important for inorganic chemicals and in cases where Log K_{ow} is not useful in view of the expected properties of the chemicals. There is no agreed Robust Study Summary template for partitioning coefficient in general, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Media *(specify whether water-soil, water-sediment, water-biota, water-air, soil-biota, air-biota)*

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
GLP: Yes [ ] No [ ] ? [ ]

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Value:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

3.4 * Aerobic Biodegradation

Aerobic Biodegradation is a **SIDS element.** The relevant Test Guidelines for Biodegradation are **OECD Test Guidelines 301, 'Ready Biodegradability' (sections A-F)** and **OECD Test Guideline 302, 'Inherent Biodegradability'(sections A-C).**

The feasibility of each OECD Test Guideline (301A-301F) frequently depends on the physical-chemical properties (e.g., stability in water), and the structure of the test substance. Testing is generally required, other than for gases, unless adequate data are already available. However, volatile substances should be tested in a closed system. For poorly soluble substances, the nature and concentration of any vehicles such as solvents and other processes that enhance the contact between the test substance and the micro-organisms should be reported.

Test results on anaerobic biodegradation as well as simulation test results should also be reported in this section. The relevant test guideline for simulation tests is draft **OECD Test Guidelines 308, 'Aerobic and Anaerobic Transformation in Aquatic Sediment Systems'**.

A Robust Study Summary template is available for Biodegradation.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed *(Include calculated as one of the possible methods)*:
Type *(test type)*: Aerobic [ ] Anaerobic [ ]
Year: *(study performed):*
Contact time *(units):*
Inoculum:

Test Conditions: (*Detail and discuss any significant protocol deviations, whether there was bacterial inhibition, and detail differences from the guideline followed including the following as appropriate:*

- *Inoculum (concentration and source):*
    - *Fresh activated sludge:*
    - *Sludge from SCAS test (concentration and time of adaptation), or*
    - *Other:*
- *Concentration of test chemical, vehicle used, pre-acclimation conditions:*
- *Temperature of incubation(°C):*
- *Dosing procedure:*
- *Sampling frequency:*
- *Appropriate controls and blank system used:*
- *Analytical method used to measure biodegradation:*

- *Method of calculating measured concentrations (i.e., arithmetic mean, geometric mean, etc.):*

Results

- Degradation % after time:
- Results:
- Kinetic *(for sample, positive and negative controls):*
  - For each time period %:
- Breakdown products: Yes [ ] No [ ]. *(If yes, describe breakdown products and whether they were transient or stable in the Remarks field for Results).*

Remarks: *(Describe additional information that may be needed to adequately assess data for reliability and use, e.g. lag time, observed inhibition, excessive biodegradation, excessive standard deviation, kinetics,, number of micro-organisms present, time required for 10% degradation and total degradation at the end of the test, e.g. 10 day window.)*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks: *(Use for any other comments necessary for clarification.)*

3.5 BOD_5, COD or ratio BOD_5/COD

Where applicable, the BOD_5, COD or ratio BOD_5/COD of the substance should be indicated although this is not a SIDS element. There is no agreed Robust Study Summary template for BOD_5, COD or ratio BOD_5/COD, however the minimum information to be reported is outlined below.

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method For BOD_5

Method:
GLP: Yes [ ] No [ ] ? [ ]

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results for BOD_5

Concentration: related to COD [ ]; DOC [ ]; Test substance [ ]
Value: (mg O_2/l)

Method For COD

Method:
GLP: Yes [ ] No [ ] ? [ ]

Results For COD

Value: (mg O_2/g)

Ratio BOD_5/COD:

Value:

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

3.6 Bioaccumulation

This is not a SIDS element. However, where appropriate data are available on bioaccumulation of the substance it should be provided. The relevant Test Guideline for this endpoint is **OECD Test Guideline 305: 'Bioconcentration: Flow-through Fish Test'**. A Robust Study Summary template is available for bioaccumulation.
The same template could also be used for reporting bioaccumulation studies in soil or sediment.

Field Name	Brief Instructions
Test Substance Identity	Chemical Name and CAS # and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations. If test material is radiolabelled, describe precise position of the labelled atom(s) and the percentage of radioactivity associated with impurities
Method	Note specific OECD, EPA, ASTM, or other method.
Species	Name species used
Exposure Period	Length of test in days. Specify period of exposure to substance (uptake phase) and period in clean water (depuration phase) if relevant.
Concentration	Concentration in test medium at which the test was performed (water, soil, sediment, pore water).
Elimination	Yes/No/No data
GLP	Yes/No
Year	Year study performed
Deviations	Yes/No (If yes, describe deviations from test guidelines)
Method of analysis	Give analytical methods used to measure substance in the test medium and test organism, along with the limit of detection and limit of quantification.
Reference substance	Yes/No (If yes, specify)
Method of analysis for reference substance	Describe briefly, if reference substance was tested
Test Conditions	
Test Solution	Describe preparation of solution of test substance. (This is particularly important for those substances believed to be poorly soluble or volatile.)
Test system/ performance	If an experimental study was performed, describe the test system and test performance: e.g. static/semistatic/flow-through test, details of apparatus/equipment, composition of test media (e.g. ingredients, solubilisers), exposure conditions (including illumination/photoperiod),

Field Name	Brief Instructions
	species tested (including holding/feeding, adaptation), number of test organisms, loading, number of replicates, details of controls, duration of uptake and depuration phase, test substance concentrations, frequency of test media quality measurements (e.g. DOC/TOC, pH, temperature), details on sampling and analysis of test species and test media samples (e.g. sampling schedule, sample preparation and analytical method)
Results	
Mortality/behaviour	Mortality and/or observed abnormal behaviour of test organisms under each exposure regime, in controls and with reference substance.
Lipid content	Lipid content of the test organisms.
Concentrations of test material during test	Concentration of test material (with standard deviation and range) for all sampling times in test organisms (total), in specific tissues thereof (e.g. lipid) and in the surrounding medium; concentration values for controls and reference compound.
Bioconcentration factor (BCF)	Calculate the steady-state BCFss and/or the kinetic BCFk (expressed in relation to the whole body, the total lipid content or specified tissues of the test organisms).
Uptake and depuration rate constants	Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration (loss) rate constants (all expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.
Depuration time	Give depuration time required for clearance of 50 % (DT50) and 90 % (DT90) of residues.
Metabolites	If identified (use of radiolabelled test material), any accumulated metabolites (accounting for > 10 % of residues) should be described.
Other Observations	Report anything unusual observations about the test, any deviations from the procedures and any other relevant information affecting results.
Conclusions Remarks	Note the study author's conclusions and whether the submitter agrees.
Reliability	Note the reliability of the study (for example "Klimisch" code). Present a rationale for the reliability code. In the case of deficiencies, discuss their impact and implications on the results. If relevant, justify the acceptability of the study
Reference	Present full citation of the study summarised.

3.7 Additional Information

This section should include other data that may be relevant to the complete initial hazard assessment of the test substance. Details such as information on how to treat the substance as well as any other information that will help to focus the assessment (either qualitative or quantitative) may be supplied. The following information should be reported for the additional data elements.

A. Sewage Treatment (Treatability of the substance)

Test Substance

Identity:

Remarks:

Results

Remarks

Reference

B. Other Information

Test Substance

Identity:

Remarks:

Results

Remarks

Reference

4. ENVIRONMENTAL TOXICITY

This section contains reporting requirements for SIDS elements and for non-SIDS elements. Data for the latter should be included because it may be applicable to the assessment of the hazard of the chemical. Where available, templates for Robust Study Summaries have been included.

It should always be clearly noted where aquatic tests were performed at measured or nominal concentration above the solubility limit in the test medium. If no mortality or other effects are observed, then the LC_{50}, EC_{50} and NOEC should be indicated as being above the stated solubility limit in the test medium. If solvents are used to enhance the solubility of poorly water-soluble substances, then this should be clearly stated. However, testing at the solubility limit, without solvents, is preferred.

For substances that decompose in water, the LC_{50}, EC_{50} and NOEC values should be expressed in terms of the measured concentration or loading of the parent substance realising that any substantial amount of breakdown product needs to be identified, quantified, or possibly tested separately.

In general, more weight should be given to studies performed in closed systems where care was taken to minimise material loss.

Specific guidance on the testing and interpretation of the results for difficult substances, e.g. poorly water-soluble substances, volatile substances, substances that degrade in the test system etc., can be found in the **OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substance and Mixtures** (Series on Testing and Assessment No 23, ENV/JM/MONO(2000)6) as well as in the OECD Guidance Document on the use of the Harmonised system for the Classification of Chemicals which are Hazardous to the Aquatic Environment (Annex 2, Section 3.5 of the Harmonised Integrated Hazard Classification System for Chemical Substances and Mixtures).

4.1 *Acute Toxicity to Fish

Acute Toxicity to Fish is a **SIDS element**. The relevant Test Guideline for Acute Toxicity to is **OECD Test Guideline 203, 'Fish, Acute Toxicity Test'.**

OECD Test Guidelines 204, 'Fish, Prolonged Toxicity Test: 14-day Study, 212, 'Fish, Short-term Toxicity Test in Embryo and Sac-Fry Stages' as well as **Test Guideline 215, 'Fish, Juvenile Growth Test'** might also be considered relevant for this element.

A Robust Study Summary template is available for Acute Toxicity to Fish.

Test Substance

Identity:

Remarks *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed *(experimental/calculated)*:
Test type *(static, semi-static, flow-through, field observation):*
GLP: Yes [ ] No [ ]
Year *(study performed):*
Species/Strain/Supplier:
Analytical Monitoring:
Exposure period*[Duration]:*
Statistical methods:

Test Conditions: (*Detail and discuss any significant protocol deviations, and detail differences from the guideline followed including the following as appropriate:*

- *Test fish (Age/length/weight, loading, pretreatment):*
- *Test conditions, for example:*
    - *Dilution water source:*
    - *Dilution water chemistry (hardness, alkalinity, pH, TOC, TSS, salinity):*
    - *Stock and test solution and how they are prepared:*
    - *Concentrations dosing rate, flow-through rate, in what medium:*
    - *Vehicle/solvent and concentrations:*
    - *Stability of the test chemical solutions:*
    - *Exposure vessel type (e.g., size, headspace, sealed, aeration, lighting, # per treatment):*
    - *Number of replicates, fish per replicate:*
    - *Water chemistry in test (D.O., pH) in the control and one concentration where effects were observed:*
- *Test temperature range:*
- *Method of calculating mean measured concentrations (i.e. arithmetic mean, geometric mean, etc.) :*

Results

Nominal concentrations *(as mg/L):*
Measured concentrations *(as mg/L):*
Unit *(results expressed in what unit):*
Element value *(e.g. LC_{50}, LC_o, LL_{50}, or LL_0 at 48, 72 and 96 hours, etc., based on measured or nominal: concentrations):*
Statistical results *(as appropriate*):

Remarks **(***Discuss if the effect concentration is greater than the solubility of the substance in the test medium. Describe additional information that may be needed to adequately assess data for reliability and use, including the following:*

- *Biological observations:*
- *Table showing cumulative mortality:*
- *Lowest test substance concentration causing 100% mortality:*
- *Mortality of controls:*
- *Abnormal responses:*
- *Reference substances (if used) – results:*
- *Any observations, such as precipitation that might cause a difference between measured and nominal values:*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

4.2 *Acute Toxicity to Aquatic Invertebrates (e.g. Daphnia)

Acute Toxicity to Aquatic Invertebrates (e.g. Daphnia) is a **SIDS element**. The relevant Test Guideline for Acute Toxicity to Aquatic Invertebrates (e.g. Daphnia) is **OECD Test Guideline 202, Part 1, 'Daphnia sp., Acute Immobilisation Test '.**

A Robust Study Summary template is available for Acute Toxicity to Aquatic Invertebrates (e.g. Daphnia).

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed *(experimental/calculated)*:
Test type *(static, semi-static, flow-through, field observation):*
GLP: Yes [ ] No [ ]
Year: *(study performed):*
Analytical Monitoring:
Species/Strain:
Exposure period *[Duration]:*
Statistical methods:

Test Conditions (*Detail and discuss any significant protocol deviations, and detail differences from the guideline followed including the following as appropriate):*

- *Test organisms*
    - *Source, supplier, any pretreatment, breeding method:*
    - *Age at study initiation:*
    - *Control group:*
- *Test conditions*
    - *Stock solutions preparation (vehicle, solvent, concentrations) and stability:*
    - *Test temperature range:*
    - *Exposure vessel type (e.g., size, headspace, sealed, aeration, number per treatment):*
    - *Dilution water source:*
    - *Dilution water chemistry (hardness, alkalinity, pH, TOC, TSS, salinity, Ca/Mg ratio, Na/K ratio):*
    - *Lighting (quality, intensity and periodicity):*
    - *Water chemistry in test (D.O., pH) in the control and at least one concentration where effects were observed:*

- *Element (unit) basis (i.e. immobilisation) :*
- *Test design (number of replicates, individuals per replicate, concentrations):*
- *Method of calculating mean measured concentrations (i.e. arithmetic mean, geometric mean, etc.):*
- *Exposure period:*
- *Analytical monitoring:*

Results

Nominal concentrations (mg/L):
Measured concentrations (mg/L):

EC_{50}, EL_{50}, LC_0, LL_0, at 24, 48 hours (clearly state unit used :
Statistical results (as appropriate):

Remarks (*Discuss if the effect concentration is greater than the solubility of the substance in the test medium. Describe additional information that may be needed to adequately assess data for reliability and use including the following as appropriate):*

- *Biological observations*

    - *Number immobilised as compared to the number exposed:*
    - *Concentration response with 95% confidence limits:*
    - *Cumulative immobilisation:*
    - *Was control response satisfactory? (yes/no/unknown):*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks: *(Use for any other comments necessary for clarification.)*

4.3 *Toxicity to Aquatic Plants (e.g. Algae)

Toxicity to Aquatic Plants (e.g. Algae) is a **SIDS element**. The relevant Test Guideline for Toxicity to Aquatic Plants (e.g. Algae) is **OECD Test Guideline 201, 'Alga, Growth Inhibition Test'.**

A Robust Study Summary template is available for Toxicity to Aquatic Plants (e.g. Algae).

Test Substance

Identity:

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed *(experimental/calculated):*
Test type *(static/other):*
GLP: Yes [ ] No [ ]
Year *(study performed):*
Species/strain # and source:
Element basis *(i.e. number of cells/ml, area under the curve, growth rate, etc.):*
Exposure period *[Duration*]:
Analytical monitoring:
Statistical methods:

Test Conditions *(Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate):*

- *Test organisms*
  - *Laboratory culture:*
  - *Method of cultivation:*
  - *Controls:*
- *Test Conditions*
  - *Test temperature range:*
  - *Growth/test medium chemistry (hardness, alkalinity, pH, TOC, TSS, dissolved oxygen, salinity, EDTA):*
  - *Dilution water source:*
  - *Exposure vessel type (e.g., size, headspace, sealed, aeration ,number per treatment):*
  - *Water chemistry in test (pH) in at least one replicate of each concentration (at start and end of the test):*
  - *Stock solutions preparation (vehicle, solvent, concentrations):*
  - *Light levels and quality during exposure:*
- *Test design (number of replicates, concentrations):*
- *Method of calculating mean measured concentrations (i.e. arithmetic mean, geometric mean, etc.):*

Results

Nominal concentrations (mg/L):
Measured concentrations (mg/L):
Unit*:*
Element value *(e.g. ErC_{50}, ErL_{50}, EbC_{50}, EbL_{50}, EC_{10}-CD, EL_{10}-CD, EC_{50}-CD, EL_{50}-CD, EL_{90}-CD, EC_{90}-CD, EC_0, or EL_0 at 24, 48, 72 or 96 hours). Note whether cells removed prior to measurement.*
NOEC, LOEC, or NOEL, LOEL:
Was control response satisfactory: Yes [ ] No [ ] Unknown [ ]
Statistical results (as appropriate):

Remarks *(Discuss if the effect concentration is greater than the solubility of the substance in the test medium. Describe additional information that may be needed to adequately assess data for reliability and use including the following):*

- *Biological observations*

    - *Cell density at each flask at each measuring point:*
    - *Growth curves:*
    - *Percent biomass/growth rate inhibition per concentration:*
    - *Observations:*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

4.4 Toxicity to Micro-organisms, e.g. Bacteria

This is not a SIDS element. Available data should be reported. The relevant Test Guideline for toxicity to aquatic micro-organisms is **OECD Test Guideline 209, 'Activated Sludge, Respiration Inhibition Test'.** Single species tests and tests on overall processes such as nitrification or soil respiration are also included in this element. The relevant Test Guideline for toxicity to soil micro-organisms is **OECD Test Guideline 216, 'Soil Micro-organisms: Nitrogen Transformation test'** as well as **217, 'Soil Micro-organisms: Carbon Transformation Test'.** There is no agreed Robust Study Summary template for Toxicity to Bacteria, however the minimum information to be reported is outlined below.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes [ ] No [ ] ? [ ]
Type: Aquatic [ ]; Field [ ]; Soil [ ]; Other [ ]
Species:
Exposure Period:

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Results: EC_{50} (h) (mg/l); EC_{xx} (h) (mg/l)
Analytical monitoring: Yes [ ] No [ ] ? [ ]

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

4.5 (*) Chronic Toxicity to Aquatic Organisms

This is a **SIDS element**, in some circumstances (see section 2.3.2)**.**

A. Chronic Toxicity to Fish

Where data are available they should be reported. The relevant Test Guideline is **OECD Test Guideline 210: 'Fish, Early –Life Stage Toxicity Test'**.

A Robust Study Summary template is available for Chronic Toxicity to Fish

Field Name	Brief Instructions
Test Substance Identity	Chemical Name and CAS # and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method. Please note if deviations from a standard method are noted.
Test Type	Static, semi-static or flow-through
Species	Provide scientific name and strain of species used
Endpoint	Indicate which endpoints were assessed, e.g. growth, mortality and survival at the embryo, larval and juvenile stages, overall mortality and survival, days to hatch, numbers hatched, lengths and weight, morphological abnormalities, behavioural effects.
Exposure Period	Length of test in days
GLP	Yes/No
Year	Year study performed
Test Conditions	
Analytical Monitoring	Yes/No
	If yes, describe or reference the analytical method used to measure the substance in water, along with the limit of detection and limit of quantification. Specify the intervals of monitoring and the statistical method used for the mean measured concentration.
Test Solution	Describe preparation of solution of test substance. (This is particularly important for those substances believed to be poorly soluble or volatile.)

Field Name	Brief Instructions
Dilution water	Give details on the source and preparation of the dilution water including the hardness, pH, oxygen content, conductance, salinity (if relevant), and any noted impurities such as: heavy metals, major anions and cations, pesticides, total organic carbon, and suspended solids.
Test organisms	Give details on tested organisms: source, collection method, age/size, kind of food, source of food, amount of food, feeding frequency, post-hatch transfer time, time to first feeding, treatment for disease within two weeks preceding test.
Handling of embryos and larvae	Describe specific exposure conditions, e.g. supporting of fertilized eggs, removing of supporting material after larvae hatch, transfer of larvae.
Test conditions	System: Describe the test chamber type (glass, stainless steel, or other chemically inert material) and the positioning of chamber. Give details on test type, renewal of TS solution, laboratory equipment, loading, replicates etc. Give relevant test conditions e.g. test temperature, dissolved oxygen, pH, adjustment of pH, aeration of dilution water, intensity of irradiation, photoperiod, load volume (g fish/litre) and test turnover time.
Examination / Sampling	Give details on what is being examined/ sampled along with examination/sampling intervals and procedures.
Statistics	Describe or refer to calculation procedures applied for determining effects data.
Results	
Range finding test	Performed / Not performed If performed, indicate test concentrations, number/percentage of animals showing adverse effects, and nature of adverse effects
Nominal and actual concentrations of test substance	Give nominal concentrations and results of measurements conducted during test (preferably in tabular form)
Effect data (including for controls)	Give the mortality/survival data at embryo, larval and juvenile stages as well as overall mortality/survival and report: - time to start of hatching and end of hatching - numbers of larvae hatching each day - length and weight of surviving animals - numbers of deformed larvae - numbers of fish exhibiting abnormal behaviour

Field Name	Brief Instructions
	Give NOEC and LOEC values (at p = 0.05) or relevant ECxx values for each response assessed; all data should be based on measured test substance concentrations in case of analytical monitoring.
Other effects (including for controls)	Describe any other observations differentiating organisms in tests and controls (e.g. loss of equilibrium, erratic swimming, hyperventilation, lethargy, changes in appearance, incidence and description of morphological abnormalities)
Conclusion	Note the author's conclusions and whether the submitter agrees
Remarks	Any further comments.
Reliability	Note the reliability of the study (for example "Klimisch" code). Present a rationale for the reliability code. In the case of deficiencies, discuss their impact and implications on the results. If relevant, justify the acceptability of the study
Reference	Present full citation of the study summarised

B. Chronic Toxicity to Aquatic Invertebrates

The relevant Test Guideline for Chronic Toxicity to Aquatic Invertebrates (e.g. Daphnia Reproduction) is **OECD Test Guideline 211, '*Daphnia magna* Reproduction Test'.**

A Robust Study Summary template is available for Chronic Toxicity to Aquatic Invertebrates.

Field Name	Brief Instructions
Test Substance Identity	Chemical name and CAS# and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	Static, semi-static, or flow-through.
GLP	Note whether Good Laboratory Practices were followed.
Year	Year study performed
Test Conditions	
Species	Name species used
Analytical Monitoring	Give analytical method used to measure chemical in water along with the limit of detection and limit of quantification.
Vehicle	If used, name the solvent/carrier in mg/L. Note whether a solvent control was used.
Temp	Note the mean (and maximum) test temperature during the test (^{o} C)
pH	Note the mean (and maximum) pH during the test.
Hardness	Report as $CaCO_3$ in mg/L
Exposure Period	Length of test in days.
Statistical method	Cite statistical methods used and appropriate reference(s).
Method Remarks	Provide the following information (if available): Test organism: source, supplier, any pretreatment, breeding method, age at study initiation and whether control group used. Test conditions: stock solution preparation (concentrations) and stability; exposure vessel type (i.e., size, headspace, sealed, aeration, number per treatment); dilution water source; dilution water chemistry (alkalinity, TOC, TSS, salinity); lighting (quality, intensity, and periodicity); water chemistry in test (DO) in the control and at least one concentration where effects were observed.

	Endpoints assessed: immobilisation, reproduction, mortality Test design: number of replicates and individuals per replicate; concentration; definitive test; range finding test results reported as measured concentration Method of calculating mean measured concentrations: i.e., arithmetic mean, geometric mean, etc.
Nominal Concentrations	Amount of chemical (preferably in mg/L) added to the test system. List all concentrations in test separated by commas.
Results	
Measured Concentrations	Amount of chemical (preferably in mg/L) measured in the test system that would represent the mean measured concentrations for the test. List all concentrations separated by commas.
Measured Concentration Remarks	List all measured data and time points consistent with the test type (static, semi-static, flow-through). Provide the N, mean, standard deviation, and range for all concentrations over the course of the test.
Precision	<, >, =, ≤, or ≥
Endpoint Type	NOEC, LOEC, MATC, LC50, or EC50
Endpoint value	Concentration associated with the endpoint type. Place numeric value here and units below.
Units	Mass per unit volume (preferably in mg/L)
Concentration Type	Note whether endpoint value is based on nominal or measured concentration.
Statistical Results	Note statistical results, with appropriate p value.
Results Remarks	Discuss whether effect concentration is greater than the water solubility of the test chemical. Include as appropriate the following: Biological observations: mortality; number of young produced in control group; concentration response with 95% confidence limits; cumulative immobilisation; was control response satisfactory; note any physiological effects observed.
Study Strengths and weakness	Comment on whether physical effects were observed, the relevance of water solubility to test results, etc.
Conclusions Remarks	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

4.6 (*)Toxicity to Terrestrial Organisms

Terrestrial toxicity tests might need to be performed at the SIDS level if significant exposure is expected or identified in the terrestrial environment (soil) compartment (see section 2.3.2).

A. Toxicity to Terrestrial Plants.

The relevant Test Guideline for this element is **OECD Test Guideline 208: Terrestrial Plants, Growth Test**

There is no agreed Robust Study Summary template for Toxicity to Terrestrial Plants, however the minimum information to be reported is outlined below.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes [ ] No [ ] ? [ ]
Type; Artificial soil [ ]; Filter paper [ ]; Other [ ]
Species:
Endpoint:Mortality [ ]; Weight [ ]; Emergence [ ]; Growth [ ]; Other [ ]
Exposure period:

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

EC_{50} (d) and/or LC_{50} (7d) and (14d) (mg/l); *(Endpoint)* EC_{50} (d) (mg/l); EC_{xx} and/or LC_{xx} (xxd) (mg/l); NOEC (mg/l); LOEC (mg/l).

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

Reference

B. Toxicity to Soil Dwelling Organisms.

The relevant Test Guideline for this element is **OECD Test Guideline 207: 'Earthworms, Acute Toxicity Test** .

There is no agreed Robust Study Summary template for Toxicity to Soil Dwelling Organisms, however the minimum information to be reported is outlined below.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes [ ] No [ ] ? [ ]
Type; Artificial soil [ ]; Filter paper [ ]; Other [ ]
Species:
Endpoint:Mortality [ ]; Weight [ ]; Emergence [ ]; Growth [ ]; Other [ ]
Exposure period:

Remarks:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

EC_{50} (d) and/or LC_{50} (7d) and (14d) (mg/l); *(Endpoint)* EC_{50} (d) (mg/l); EC_{xx} and/or LC_{xx} (xxd) (mg/l); NOEC (mg/l); LOEC (mg/l).

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

C. Toxicity to Other Non Mammalian Terrestrial Species (including Avian)

Taking into account animal welfare considerations, the need for avian toxicity testing should only be considered at the post-SIDS stage. The relevant Test Guidelines for this element are:

OECD Test Guideline 205: Avian Dietary Toxicity Test
OECD Test Guideline 206: Avian Reproduction Test
OPPTS Test Guideline 860.2100: Avian Acute Oral Toxicity Test

Results of toxicity towards soil micro-organisms can be reported either in this section or in section 4.4 'Toxicity to Micro-organisms, e.g. Bacteria'. The relevant Test Guidelines for this element are:

OECD Test Guideline 216: Soil Micro-organisms: Nitrogen Transformation Test
OECD Test Guideline 217: Soil Micro-organisms: Carbon Transformation Test

There is no agreed Robust Study Summary template for Toxicity to Other Non Mammalian Terrestrial Species (including Avian), however the minimum information to be reported is outlined below.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes [ ] No [ ] ? [ ]
Species:
Endpoint: Mortality [ ]; Reproduction rate [ ]; Weight [ ]; Other [ ]
Exposure period:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Results: LD_{xx} or $LC_{xx\ (xxd)}$ (mg/kg); NOEC (mg/kg); LOEC (mg/kg).

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

4.6.1. Toxicity to Sediment Dwelling Organisms

This is not a SIDS element. Available data should be reported. Test Guidelines for toxicity to sediment dwelling organisms are under development: **OECD Test Guideline Proposal 218 'Sediment-Water Chironomid Toxicity Test Using Spiked Sediment' and OECD Test Guideline Proposal 219 'Sediment-Water Chironomid Toxicity Test Using Spiked Water'**.

A Robust Study Summary template is suggested for toxicity tests to sediment dwelling organisms.

Field Name	**Brief Instruction**
Test Substance	
Identity	Chemical name and CAS# and EINECS#
Test Substance Remarks	- Purity of material tested, impurities and their concentrations, - If product, give composition, - If used, name of the solvent/carrier and concentration in mg/L (reported to the water column) or in mg/kg d.w. (related to the sediment). Note whether a solvent control was used
Method	
Method	Note OECD draft proposal, ASTM or other (with the year of publication or updating of the method used)
GLP	Note whether Good Laboratory Practices were followed
Year	Year study performed
Method Remarks	- Note whether the substance is initially added to the sediment or the water column - Note the type of test : static, semi-static, flow through, field test, other
Test Conditions	
Species	Name species used
Endpoints	Mortality / Growth / Emergence / Development / Reproduction (several endpoints are possible)
Exposure Period	Length of test in days
Test Conditions Remarks	- Formulated or natural sediment, - (water only tests should be reported in the relevant aquatic toxicity e.g. toxicity to invertebrates sections).

	- Description of the characteristics of the sediment: TOC content, size of the particles. If formulated, give the composition, if natural, give its origin, - Water source (natural, reconstituted) and chemistry, pH, hardness, TOC, salinity), - Test design: number of replicates and individuals per replicate, number of concentrations, concentrations of tests substance, - Method used for addition of the substance to sediment or water, if any specify the period and the conditions for equilibration, - Monitoring of concentration of test substance: "yes/no", - Give analytical method used to measure chemical in water and sediment along with the limit of detection and limit of quantification, - Exposure vessel type (e.g., size, headspace, sealed, aeration, lighting), - Method of calculating mean measured concentrations: i.e., arithmetic mean, geometric mean, etc, - Note the test temperature range (minimum-maximum) in the water (°C), the pH range (minimum-maximum) in the water, the dissolved oxygen concentration range in the water during the test, - Source, breeding method, age and selection of the organisms at study initiation, use of any control group, - Information about feeding of test organisms, source of food, possibly contamination of food.
Results	
Unit	mg/l, mg/kg d.w., mg/kg OC d.w., other
Concentration type	Note whether endpoint value is based on nominal or measured concentration
Measured concentrations	Amount of chemical in sediment (mg/kg) and in water (mg/l) (distinguish between pore water and overlying water) measured in the test system that would represent the mean measured concentrations for the test
Precision	<, >, =, ≤, ≥ or ca. (circa)
Endpoint Type	NOEC, NOELR, LOEC, LOELR, LC50, LL50, ECxx, ELxx

Endpoint Value	Concentration associated with the endpoint type. If appropriate, results can be reported in table format for different effects measured in the test (e.g. table below)
Results Remarks	- List all measured data and provide the N, mean, standard deviation and range for all concentrations over the course of the test, - Discuss the stability of the test substance over the test duration, - Cite statistical methods used, p values, 95% confidence limits and appropriate reference(s), - Biological observations: mortality, organisms not recovered at the end of the test, development, growth, number of egg mass or young produced, any behaviour or physiological effects, - Note control performances and if validity criteria are met, - If used, note the results with a reference substance.
Conclusion	Note the study's author's conclusions and whether the submitter agrees
Reliability	
Reliability code	Note the reliability of the study (for example "Klimisch" code)
Reliability Remarks	Present rationale for the reliability code
Reference	Present full citation of the study summarised
General Remarks	Use for any other comments necessary for clarification

Results table

Endpoint: e.g. mortality, sublethal effects, growth, emergence, development, reproduction.					
Nominal concentration (unit)	Measured concentration (unit)	7d	14d	21d	28d
Conc. 1					
Conc. 2					
Conc. 3					
…					

4.7 Biological Effects Monitoring (including Biomagnification)

This is not a SIDS element. Available data should be reported in this section. Studies on variation of predominant species in certain ecosystems (e.g. mesocosm) and monitoring of biological effects should be included here.

There is no Robust Study Summary template for Biological Effects Monitoring (Including Biomagnification), however the minimum information to be reported is outlined below.

Test Substance

Identity (purity) :

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Species or ecosystem studied:
Effects monitored:

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Chemical analysis:

Remarks: *(Information on environmental conditions (e.g. water characteristics: suspended matter, pH, temperature, hardness; soil/sediment characteristics: % organic matter, clay content)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

4.8 Biotransformation and Kinetics

This is not a SIDS element. Available data should be reported. Included in this item are studies on absorption, distribution, metabolism and excretion etc.

There is no agreed upon Robust Study Summary template for Biotransformation and Kinetics, however the minimum information to be reported is outlined below.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Type: Animal [ ]; Aquatic [ ]; Plant [ ]; Terrestrial [ ]; Other [ ]

Test Conditions: *(Detail and discuss any significant protocol deviations.)*

Results

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

4.9 Additional Information

This section may be used to include other data that may be relevant to the complete initial hazard assessment of the test substance. The following information should be reported for each additional data element.

Test Substance

Identity (purity):

Remarks:

Results

Remarks:

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

Reference

5. MAMMALIAN TOXICITY

This section includes the reporting requirements for SIDS elements and for non-SIDS elements. The latter data should be included when available because they may be applicable to the assessment of the hazard of the chemical. Where available, templates for Robust Study Summaries have been included.

With the exception of data on irritation and sensitisation, observations on humans should be reported under Experience with Human Exposure, Section 5.11. Observations on humans regarding irritation and sensitisation can be reported in sections 5.3 and 5.4.

5.1 Toxicokinetics, Metabolism and Distribution

This is not a required SIDS element. Available data should be reported, since they may be valuable in the design for filling required SIDS elements and in the interpretation of other test data. The relevant Test Guideline is **OECD Test Guideline 417: 'Toxicokinetics'**.

An agreed Robust Study Summary template is available for Pharmacokinetics.

Field Name	Brief Instructions
Test Substance	Chemical name and CAS# and EINECS#
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	Note whether in vivo or in vitro**.**
GLP	If applicable, note whether Good Laboratory Practices were followed.
Year	Year study performed.
Method	Provide a short description of the method used, if not OECD, EPA, ASTM. Also, if standard method used, list protocol deviations that may (or may not) affect interpretation. Describe any PK models used. Additional details: whether animals were fasted, fasting period, etc. For studies investigating metabolism, note the use of any enzyme inhibitors or inducers. For in vitro skin (or other) penetration studies: describe the nature of the preparation (e.g., full thickness skin, dermatomed skin, artificial membrane, etc.); note whether skin was used fresh, stored, or frozen prior to use; state whether the test was conducted using a static or flow through cell (note the flow rate); and state the composition of the receptor fluid.
Test Conditions	
Species	Species used (rabbit, rat, etc.).
Strain	Strain of chosen species (i.e., New Zealand White rabbit).
Sex	Male/Female/Both.
Cell Type	If in vitro, list cell line or cell type used or tissue preparation (e.g., liver slice).
Age	Approximate age of animals.
Body weight	Body weight range of test animals.
Number of Animals/Donors	Number used (per sex if both used).

Route	Route of exposure. If inhalation, note whether nose-only or whole body.
Vehicle	If vehicle used, identify and note volume.
Dose(s) used	Amount and/or concentrations used (in mg/kg, mg/m3, etc.). Describe frequency of dose and/or exposure period and sampling times to assess kinetics. For studies of dermal penetration, describe the procedure used to decontaminate the skin at the end of the exposure period. Include description of control group.
Statistical Methods	Describe statistical methods used.
Actual Dose(s)	Measured or actual doses/exposure concentrations achieved..
Excretion Routes	List all routes of excretion monitored in study (urine, faeces, exhaled air, etc.). Provide sampling times. For skin penetration studies, include details on measurement of skin residues.
Body Fluids Sampled	List all body fluids monitored (blood, cerebrospinal fluid, etc.). Provide sampling times.
Tissues Sampled	List all body tissues monitored. (fat, liver, brain, etc.). Provide sampling times.
Metabolites	List all metabolites measured.
Metabolites CAS	List CAS numbers of all metabolites.
Results	Provide detailed results for all parameters; including percentage absorbed (bioavailability), half-life information, Km, Vmax, and similar measures (for skin penetration studies include flux and permeability coefficient). Also note the routes of elimination for each metabolite.
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

5.2 *Acute Toxicity

Acute Toxicity is a **SIDS element**. Testing is generally required if adequate data are not available, but only on the most relevant route of exposure. With a few exceptions, all substances should be tested by the oral route. Gases and vapours should be tested only by the inhalation route. Dependent upon the most important route of human exposure and physical-chemical properties of the substance, the dermal or the inhalation route could also be considered. Further guidance on acute toxicity testing is provided in Chapter 2 (section 2.3.2).

A. Acute oral toxicity

The relevant Test Guidelines for Acute oral Toxicity testing is:

OECD Test Guideline 420:	**Acute Oral Toxicity-Fixed Dose Method.**
OECD Test Guideline 423	**Acute Oral Toxicity - Acute Toxic Class Method**
OECD Test Guideline 425	**Acute Oral Toxicity - Up-and-Down Procedure**

OECD Test Guideline 401, 'Acute Oral Toxicity' has been replaced with the above listed Test Guidelines and is not to be used anymore. Data generated with this guideline after 17 December 2002 cannot be accepted to fulfil the SIDS element.

An agreed Robust Study Summary template is available for Acute Oral Toxicity

Test Substance *(Use for any pertinent, test substance-specific remarks.)*

Identity (purity):

Remarks:

Method

Method/guideline followed *(experimental/calculated)*:
Type *(test type):*
GLP: Yes [ ] No [ ]
Year *(study performed):*
Species/Strain:
Sex:
No. of animals per sex per dose:
Vehicle:
Route of administration *(if inhalation-aerosol, vapour, gas, particulate*):

Test Conditions: (*Detail and discuss any significant protocol deviations, and detail differences from the guideline followed including the following as appropriate):*

- *Age:*
- *Doses (OECD guideline 425 does not provide dose levels, so this must be described in detail):*
- *Doses per time period:*
- *Volume administered or concentration:*
- *Post dose observation period:*
- *Exposure duration (for inhalation studies):*

Results

Value ([LD50 or LC50] with confidence limits if calculated):
Number of deaths at each dose level:

Remarks *(Describe 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):*
- *Description, severity, time of onset and duration of clinical signs at each dose level:*
- *Necropsy findings, included doses affected, severity and number of animals affected:*
- *Potential target organs (if identified in the report:)*
- *If both sexes tested, results should be compared*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

B. Acute inhalation toxicity

The relevant Test Guideline for acute inhalation toxicity testing is:

OECD Test Guideline 403: Acute Inhalation Toxicity

The same Robust Study Summary template as for acute oral toxicity can be used to report available key studies.

C. Acute dermal toxicity

The relevant Test Guideline for acute dermal toxicity testing is:

OECD Test Guideline 402: Acute Dermal Toxicity

The same Robust Study Summary template as for acute oral toxicity can be used to report available key studies.

D. Acute toxicity, other routes

Testing is normally not required for other routes of administration, e.g. intramuscular, intraperitoneal, intravenous or subcutaneous, but available results can be reported here. The same Robust Study Summary template as for acute oral toxicity can be used to report available key studies.

5.3 Corrosiveness/Irritation

A. Skin Irritation/Corrosion

This is not a required SIDS element. When available, data should be reported. **OECD Test Guideline 404, 'Acute Dermal Irritation/Corrosion**' might be considered relevant for the endpoint of Skin Irritation/Corrosion**.**

An agreed Robust Study Summary template is available for Skin Irritation.

Field Name	Brief Instructions
Test Substance	Chemical name and CAS# and EINECS#
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
pH	Note pH of test material
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	In vitro or in vivo
GLP	Note whether Good Laboratory Practices were used.
Year	Year study performed.
Test Conditions	
Species	Name species used
Strain	Name strain used.
Cell type	Name cell type or line (in vitro test).
Sex	Males, females or both
Number of animals per sex per dose	Self-explanatory
Total dose	Note amount of test material applied to skin (mg)
Vehicle	If a vehicle was used, identify and note volume.
Exposure time period	Length of time test material is in contact with animal/cell.
Grading scale	Please specify the scale/grading system used.
Method Remarks	Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate (if applicable): Controls, area of exposure (body part and surface area); occluded or not; shaved or not; abraded or not; prior treatment of test site; grading

	time points.
Results	Cumulative total and percent responders
Primary irritation index	Note score
Results Remarks	Describe additional information that may be needed to adequately assess data for reliability and use, including the following (if available and applicable): note whether the substance is a skin sensitiser (if known); numerical skin grades at 1, 4, 24, and 72 hours; delayed grading scores at 7 to 14 days; whether the effects observed were reversible; note erythema/edema findings; and note other dermal lesions and/or systemic effects.
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

B. Eye Irritation/Corrosion

This is not a SIDS element. When available test data should be reported. **OECD Test Guideline 405, 'Acute Eye Irritation/Corrosion**' might be considered relevant for the endpoint of Eye Irritation/Corrosion.

An agreed Robust Study Summary template is available for Eye Irritation.

Field Name	Brief Instructions
Test Substance	Chemical Name and CAS# and EINECS#
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
pH	Note pH of test substance
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	Note whether in vivo or in vitro
GLP	Note whether Good Laboratory Practices were followed.
Year	Year study performed.
Method Remarks	Provide a short description of the method used if not OECD, EPA, ASTM (ex: Draize or modified Draize). Also, if standard method used, list protocol deviations that may (or may not) affect

	interpretation. Additional details: whether anesthetics or vehicles were used and when and whether eyes were washed out with water.
Test Conditions	
Species	Note species used
Strain	Note strain of species used
Cell Line	If in vitro method, list cell type/line
Sex	Male/Female/Both
Number of animals per dose	Self-explanatory
Dose(s) used	The amount and/or concentrations used (in ml and/or mg per eye).
Observation period	List the time points at which grading/scoring took place (i.e., 1 hour, 24 hours, 14 days, etc.)
Scoring Method Used	Name method used to score irritation.
Corrosive	Yes or no
Irritation Score: Cornea/Iris	0-4; 0-2
Irritation Score: Conjunctivae (Redness/Chemosis)	0-3; 0-4
Overall Irritation Score	Provide total score here.
Tool used to assess score	Hand-slit lamp, biomicroscope, fluorescein
Description of lesions (if seen)	Describe any lesions observed that may be treatment-related
Results Remarks	Note # of animals affected, whether scores were reduced over time (up to 21 days); and whether effects were reversible
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

5.4 Skin Sensitisation

This is not a required SIDS element. When data are available they should be reported. **OECD Test Guideline 406, 'Skin Sensitisation' and 429, 'Skin Sensitisation: Local Lymph Node Assay**' might be considered relevant for the endpoint of Skin Sensitisation.

An agreed Robust Study Summary template is available for Skin Sensitisation.

Field Name	Brief Instructions
Test Substance	Chemical name and CAS# and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	Challenge, cellular proliferation (e.g., LLNA)
GLP	If applicable, note whether Good Laboratory Practices were followed.
Year	Year study performed.
Test Conditions	
Species	Name species used
Strain	Name strain used.
Sex	Males, females or both
Number of animals per sex per dose	Self-explanatory
Route of administration	Injection/topical. Note whether with or without an occluded patch, and the type of patch used.
Induction concentration	List concentration(s) of test substance separated by commas. Note whether more than one dose was given and the spacing between doses. If applicable, mention any pre-treatment that may have been conducted.
Induction vehicle	If a vehicle was used, identify and note volume.
Challenge concentration	(If applicable)
Challenge vehicle	(If applicable)
Grading system used	Identify the grading system used (traditional tests). For other, non-traditional tests (i.e., LLNA), identify the endpoint to measure effect (e.g., proliferation of lymph nodes).

Method Remarks	Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate (if applicable): Age of animal at study initiation; positive and negative controls; results of range-finding or screening studies; justification for vehicles; volume of material dosed; describe patch if used; duration of exposure for induction; length of rest period between induction and challenge; duration of exposure for challenge; description of rechallenge.
Results	Note whether the test substance is positive, negative or equivocal. Provide a narrative specifying whether or not the test substance is considered a sensitiser (under conditions of test). Include what response is required in the test to constitute a sensitiser.
Grades	List (if used).
Results Remarks	Describe additional information that may be needed to adequately assess data for reliability and use, including the following (if available and applicable): note whether the substance was a skin irritant at the tested concentrations; number of animals with skin grades of 0, 1, 2, and 3 at each observation time; 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; and results of rechallenge. In addition, if the study was an LLNA, provide the following: group mean disintegrations/minute and standard deviation; stimulation index or fold increase for each group (including positive control) relative to negative control; and statistical comparisons of groups mean dpms compared to controls.
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

5.5 *Repeated Dose Toxicity

Repeated Dose Toxicity is a **SIDS element**. The relevant Test Guidelines for Repeated Dose Toxicity are:

OECD Test Guideline 407: Repeated Dose 28-day Oral Toxicity Study in Rodents.
OECD Test Guideline 410: Repeated Dose Dermal Toxicity: 21/28-day Study
OECD Test Guideline 412: Repeated Dose Inhalation Toxicity: 28-day or 14-day Study

OECD Test Guideline 422, 'Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test' is also acceptable. Guidance on test selection can be found in Chapter 2 (section 2.3.2).
If data on repeated dose toxicity over longer durations or even chronic toxicity is available, they can also be reported in this section.

When determining adequacy of existing data, the duration of exposure is a key consideration in addition to details about the test species, the route of exposure and the quality of data.

An agreed Robust Study Summary template is available for Repeated Dose Toxicity.

Test Substance

Identity (purity):

Remarks: *(Use for any pertinent, test substance-specific remarks.)*

Method

Method/guideline followed:
Test type:
GLP: Yes [ ] No [ ]
Year (*study performed*):
Species:
Strain:
Route of administration, oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other:
Duration of test:
Doses/concentration levels:
Sex:
Exposure period:
Frequency of treatment:
Control group and treatment:
Post exposure observation period:
Statistical methods:

Test Conditions (*Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate):*

- *Test Subjects*
  - *Age at study initiation:*
  - *No. of animals per sex per dose:*

- *Study Design*

    - *Vehicle:*
    - *Satellite groups and reasons they were added:*
    - *Clinical observations performed and frequency (clinical pathology, functional observations, etc.):*
    - *Organs examined at necropsy (macroscopic and microscopic):*

Results

NOAEL (NOEL):
LOAEL (LOEL):
Actual dose received by dose level by sex (if known):
Toxic response/effects by dose level:
Statistical results (as appropriate)

Remarks (*Describe additional information that may be needed to adequately assess data for reliability and use, including the following if available. Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen:*

- *Body weight:*
- *Food/water consumption:*
- *Description, severity, time of onset and duration of clinical signs:*
- *Ophthalmologic findings incidence and severity:*
- *Haematological findings incidence and severity:*
- *Clinical biochemistry findings incidence and severity:*
- *Mortality and time to death:*
- *Gross pathology incidence and severity:*
- *Organ weight changes:*
- *Histopathology incidence and severity* :

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

5.6 *Genetic Toxicity *in vitro*

Genetic Toxicity *in vitro* is a **SIDS element.** The relevant Test Guidelines for Genetic Toxicity are **OECD Test Guidelines 471, 473, 474, 475 and 476.**

Results on two different endpoints should be available, generally gene mutation and chromosomal aberration. These endpoints may be evaluated by using the following tests:

- Gene mutation in prokaryotic cells, should be performed preferably in *Salmonella typhimurium* (e.g. **OECD Test Guideline 471, 'Bacterial Reverse Mutation Test'**). The chemical class of the test substance may determine which test organism and whether modified procedures may be needed. The test should be carried out with and without metabolic activation. **OECD Test Guideline 476, '*In vitro* Mammalian Cell Gene Mutation Test'** is also relevant for the evaluation of Genetic Toxicity.

- Chromosomal aberration may be evaluated in mammalian cells grown *in vitro* (e.g. **OECD Test Guideline 473, '*In vitro* Mammalian Chromosomal Aberration Test'**) or by *in vivo* methods (see Item 5.7)

When determining if additional testing is required, the quality of data, the nature of the test organism, strain and/or cell system and information on whether metabolic activation was addressed are important considerations.

A. Gene Mutation

The relevant Test Guidelines for this element are:

OECD Test Guideline 471: Bacterial Reverse Mutation Test
OECD Test Guideline 476: *In vitro* Mammalian Cell Gene Mutation Test'

An agreed Robust Study Summary template is available for Gene Mutation.

Test Substance

Identity (*purity*):

Remarks (Use for any pertinent, test substance-specific remarks.):

Method

Method/guideline followed:
Type (e.g. bacterial reverse mutation assay, bacterial gene mutation study, cytogenetic assay, mammalian cell gene mutation assay, cytogenetic assay, etc.):
System of testing (bacterial, non bacterial):
GLP: Yes [ ] No [ ]
Year (study performed):
Species/Strain or cell type and or cell line (bacterial or non-bacterial):
Metabolic activation:

- Species and cell type:
- Quantity:
- Induced or not induced:
- Chemical used for induction:

Concentrations tested:
Statistical Methods:

Test Conditions: *(Detail and discuss any significant protocol deviations. Detail differences from the guideline followed including the following as appropriate):*

- *Test Design*
  - *Number of replicates:*
  - *Frequency of Dosing:*
  - *Positive and negative control groups and treatment:*
  - *Number of metaphases analyzed:*
- *Solvent:*
- *Description of follow up repeat study:*
- *Criteria for evaluating results(e.g. cell evaluated per dose group):*

Results

Cytotoxic concentration:

- With metabolic activation:
- Without metabolic activation:

Genotoxic effects (e.g. positive, negative, unconfirmed, dose-response, equivocal):
- With metabolic activation:
- Without metabolic activation:

Statistical results, as appropriate:

Remarks *(Note 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. Describe additional information that may be needed to adequately assess data for reliability and use, including the following if available. Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen):.*

- *Frequency of reversions/mutations/aberrations, polyploidy as appropriate:*
- *Precipitation concentration if applicable:*
- *Mitotic index:*

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made).*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*
Remarks *(Use for any other comments necessary for clarification.)*

B. Chromosomal Aberration

The relevant Test Guideline for this element is:

OECD Test Guideline 473: *In vitro* Mammalian Chromosomal Aberration Test'

The same Robust Study Summary templates as proposed for gene mutations can be used for reporting key studies on chromosomal aberrations.

5.7 (*) Genetic Toxicity *in vivo*

If one of the test results on genetic toxicity *in vitro* is positive, it is necessary to perform a test on genetic toxicity *in vivo* such as the micronucleus test or metaphase analysis of bone marrow cells. The relevant test guidelines are:

OECD Test Guideline 474	**Mammalian Erythrocyte Micronucleus Test**
OECD Test Guideline 475	**Mammalian Bone Marrow Chromosomal Aberration Test**

OECD Test Guideline 483, 'Mammalian Spermatogonial Chromosome Aberration Test' might also be applicable to this endpoint**,** as well as **OECD Test Guideline 486,'Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells *in vivo*'.**

When determining if additional testing is required, the quality of data, the nature of the test organism, strain and/or cell system and information on whether metabolic activation was addressed are important considerations.

An agreed Robust Study Summary template is available for Genetic Toxicity *in vivo.*

Test Substance

Identity *(purity)*:

Remarks: (Use for any pertinent, test substance-specific remarks.)

Method

Method/guideline followed
Type *(test type, e.g. micronucleus assay etc…)*
GLP: Yes [ ] No [ ]
Year *(study performed*
Species
Strain
Sex
Route of administration (if inhalation – aerosol, vapour, gas, particulate)
Doses/concentration levels
Exposure period
Statistical methods

Test Conditions*: (Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate:*

- *Age at study initiation*
- *No. of animals per dose*
- *Vehicle*
- *Duration of test*
- *Frequency of treatment*
- *Sampling times and number of samples*
- *Control groups and treatment*

- *Clinical observations performed (clinical pathology, functional observations, etc.)*
- *Organs examined at necropsy (macroscopic and microscopic)*
- *Criteria for evaluating results (for example, cell types examined, number of cells counted in a mouse micronucleus test)*
- *Criteria for selection of maximum tolerated dose (M.T.D).*

Results

Effect on mitotic index or PCE/NCE ratio by dose level by sex
Genotoxic effects (positive, negative, unconfirmed, dose-response, equivocal)
NOAEL(NOEL) (C)/LOAEL(LOEL) (C)
Statistical results (as appropriate)

Remarks (Describe 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, as appropriate
- 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

Conclusions

Remarks: *(Identify source of comment, i.e. author and/or submitter)*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

5.8 Carcinogenicity

This is not a SIDS element. When data are available they should be reported.

A Robust Study Summary template is outlined below.

Field Name	Brief Instructions
Test Substance	Chemical name and CAS# and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method.
Test Type	Indicate type of test e.g. lifelong bioassay, initiation/promotion, transgenic, neonatal mouse or other.
GLP	If applicable, note whether Good Laboratory Practices were followed.
Year	Year study performed.
Test Conditions	
Species	Name species used
Strain	Name strain used.
Sex	Males, females or both
Number of animals per sex per dose Age of animals Weight at study initiation	Self-explanatory
Route of administration	Oral feed, drinking water, gavage, dermal, inhalation, implantation, infusion, i.v., i.p., s.c., i.m.
Exposure period	
Frequency of treatment	Describe, e.g. ‘7d/wk’ or ‘continuous’
Post Exposure Observation Period	Describe, e.g. ‘none’ or ’14 days’
Doses	Note the values of the doses/concentrations and unit
Control Group	Yes; yes, concurrent no treatment; yes, concurrent vehicle; yes historical; no.
FOR ORAL STUDIES	
Vehicle	e.g. moistened with water, aqueous solution, corn oil, etc.

Concentration in vehicle	
Total volume applied	
FOR INHALATION STUDIES	
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. 10% of body surface
Occlusion	e.g. semi-occlusive
Vehicle	
Concentration in vehicle	
Total volume applied	
Removal of test substance	e.g. water or solvent
Test Conditions	
CLINICAL OBSERVATIONS AND FREQUENCY	Indicate clinical observations performed (Yes/No) and give frequency of examination and number of animals examined where appropriate.
Body weight	
Food consumption	
Water consumption	
Clinical signs	
Mortality	
Macroscopic examination	
Ophtalmoscopic examination	
Haematology	Number of animals: all animals / 10 animals per sex and group / other; Time points: After 3, 6, 12, 18, 24 months of treatment /end of study / other; Parameters: Haematocrit, haemoglobin concentration,erythrocyte count, total and differential leukocyte count, platelet count, clotting time, prothrombin time, thromboplastin time)
Clinical chemistry	Number of animals/Time points: see Haematology; Parameters: Sodium, potassium, glucose, total cholesterol, urea, blood urea nitrogen, total bilirubin, creatinine, total protein and albumin, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, gamma glutamyl transpeptidase, sorbitol dehydrogenase, methaemoglobin, lipids, hormone (specify hormones), acid/base balance, cholinesterase inhibition)
Urinalysis	Number of animals/Time points: see Haematology; Parameters: Appearance, volume, osmolality, specific gravity, pH, protein, glucose, blood)
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC)	Indicate organs examined including organ weights if measured. Note if not all dose groups were examined.

Macroscopic	Time points: All surviving animals / at interim sacrifice / at terminal sacrifice; Organs: Liver, kidneys, adrenals, testes, epididymides, uterus, ovaries, thymus, spleen, brain, heart)
Microscopic	Examined dose groups: All dose groups / high dose group and controls / other dose groups, if any effect Time points: All surviving animals / at interim sacrifice / at terminal sacrifice; Organs: Brain, spinal cord, pituitary, thyroid, parathyroid, thymus, oesophagus, salivary glands, stomach, small and large intestines, liver, pancreas, kidneys, adrenals, spleen, heart, trachea, lungs, aorta, gonads, uterus, female mammary gland, prostate, urinary bladder, gall bladder (mouse), lymph node, peripheral nerve, bone marrow, skin, eyes)
OTHER EXAMINATIONS	e.g. enzyme induction, cell proliferation, reversibility of effects
STATISTICAL METHODS	Describe methods used
REMARKS	Indicate and discuss any significant protocol deviations and detail differences from the guideline followed. Also include the following if available: rationale for dose selection; satellite groups and why added.
Results	Describe the relevant findings. If no effects occurred, explicitly note "No effects"
Mortality and time to death Clinical signs Body weight gain Food/Water consumption Ophthalmoscopic examination Clinical chemistry Haematology Urinalysis Organ weights Gross Pathology Histopathology	Indicate number died per sex per dose and time to death.
Time to tumors	For dermal route and skin tumours: give mean time until appearance of tumour or time until appearance of first tumour or other measure.
Statistical results	Unless already described with specific test results above.
Conclusions	Note the study author’s conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, “Klimisch” code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

5.9 *Reproductive Toxicity (including Fertility and Developmental Toxicity).

Reproduction Toxicity is a **SIDS element,** which requires data on both fertility and developmental toxicity.

A. Fertility

Requirements for fertility data can be met through use of **OECD Test Guideline 415: One-Generation Reproduction Toxicity Study** or **OECD Test Guideline 416: Two-Generation Reproduction Toxicity Study.**

In addition, **OECD Test Guideline 421,** '**Reproduction/Developmental Toxicity Screening Test'** or **OECD Test Guideline 422, 'Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test'** can also be used as discussed in Section 2.3.2.

An agreed Robust Study Summary template is available for the fertility endpoint.

Test Substance

Identity (purity):

Remarks *(Use for any pertinent, test substance-specific remarks):*

Method
Method/guideline followed:
Type *(one generation, two generation, etc.)*:
GLP: Yes [ ] No [ ]
Year *(study performed):*
Species:
Strain:
Route of administration: - oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other:
Doses/concentration levels:
Sex:
Control group and treatment:
Frequency of treatment:
Duration of test:
Premating exposure period for males (P and F_1) as appropriate:
Premating exposure period for females (P and F_1) as appropriate:
Statistical methods:

Test Conditions*: (Detail and discuss any significant protocol deviations, and detail differences from the guideline followed, including the following as appropriate):*

- *Test animals*
    - *Number, age, sex per dose for P, F1 and F2, if appropriate:*
- *Test design*

- *Vehicle:*
- *Dosing schedules and pre and post dosing observations periods for P, F1 and F2, if appropriate:*

- *Mating procedures (M/F ratios per cage, length of cohabitation, proof of pregnancy):*
- *Standardisation of litters (yes/no and if yes, how and when):*
- *Parameters assessed during study P and F1 as appropriate:*

  - *Clinical observations performed and frequency (clinical pathology, functional observations, etc.):*
  - *Estrous cycle length and pattern (number of days spent in each phase):*
  - *Sperm examination (epididymal or vas sperm, concentration, motility, morphology):*

- *Parameters assessed during study F1 and F2, as appropriate:*
  - *Clinical observations performed and frequency (weight gain, growth rate, etc.):*
  - *Others, for example anogenital distance, if performed:*
  - *Organs examined at necropsy (macroscopic and microscopic):*

Results

NOAEL (NOEL) and LOAEL (LOEL) for P, F1 and F2, as appropriate:
Actual dose received by dose level by sex if known:
Parental data and F1 as appropriate *(toxic response/effects with NOAEL value). Provide at a minimum qualitative descriptions of elements where dose related observations were seen:*
Offspring toxicity F1 and F2, as appropriate *(toxic response/effects with NOAEL value). Provide at a minimum qualitative descriptions of elements where dose related observations were seen.*
Statistical results (as appropriate):

Remarks *(Describe additional information that may be needed to adequately assess data for reliability and use. Include the following when there are dose related effects if available):*

- *Parental data and F1 as appropriate, provide at a minimum qualitative descriptions of elements where dose related observations were seen:*
- *Body weight:*
- *Food/water consumption:*
- *Description, severity, time of onset and duration of clinical signs:*
- *Fertility index (pregnancies/matings):*
- *Precoital interval (w/number of days until mating and number of oestrous periods until mating):*
- *Duration of gestation (calculated from day 0 of pregnancy):*
- *Gestation index (live litters/pregnancies):*
- *Changes in lactation:*
- *Changes in oestrous cycles:*
- *Effects on sperm:*
- *Haematological findings incidence and severity:*
- *Clinical biochemistry findings incidence and severity:*
- *Mortality:*
- *Gross pathology incidence and severity:*
- *Number of implantations:*
- *Number of corpora lutea (recommended):*
- *Ovarian primordial follicle counts:*

- *Organ weight changes:*
    - ♦ *Histopathology incidence and severity:*
- *Offspring toxicity F1 and F2, as appropriate, provide as a minimum qualitative descriptions of elements where dose related observations were seen:*
- *Litter size and weights:*
- *Sex and sex ratios:*
- *Viability index (pups surviving 4 days/total births):*
- *Post natal survival until weaning:*
- *Effects on offspring (grossly visible abnormalities):*
- *Postnatal growth, growth rate:*
- *Vaginal opening (F) or preputial separation (M):*
- *Other observations, for instance anogenital distance, if measured:*
- *Organ weights:*

Gross pathology:

Conclusions

Remarks *(Identify source of comment, i.e. author and/or submitter):*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

B. *Developmental Toxicity

Developmental Toxicity **is a SIDS Element.** The relevant Test Guideline is **OECD Test Guideline 414, 'Prenatal Developmental Toxicity Study'. OECD Test Guideline 421, 'Reproduction/Developmental Toxicity Screening Test'** or **OECD Test Guideline 422, 'Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test'** can also be used in certain circumstances as discussed in Section 2.3.2.

An agreed Robust Study Summary template is available for Developmental Toxicity.

Test Substance

Identity (purity):

Remarks *(Use for any pertinent, test substance-specific remarks.):***Method**
Method/guideline followed:
GLP: Yes [ ] No [ ]
Year *(study performed):*
Species:
Strain:
Route of administration - oral (gavage, drinking water, feed), dermal, inhalation (aerosol, vapour, gas, particulate), other:
Doses/concentration levels:
Sex:
Exposure period:
Frequency of treatment:
Control group of treatment:
Duration of test:
Statistical methods:

Test Conditions: *(Detail and discuss any significant protocol deviations, and detail differences from the guideline followed, including the following as appropriate):*

- *Age at study initiation:*
- *Number of animals per dose per sex:*
- *Vehicle:*
- *Clinical observations performed and frequency :*
- *Mating procedures (M/F ratios per cage, length of cohabitation, proof of pregnancy):*
- *Parameters assessed during study (maternal and fetal):*
- *Organs examined at necropsy (macroscopic and microscopic):*

Results

NOAEL (NOEL) and LOAEL (LOEL) maternal toxicity:
NOAEL (NOEL) and LOAEL (LOEL) developmental toxicity:
Actual dose received by dose level by sex if available:
Maternal data with dose level *(with NOAEL value) (Provide at a minimum qualitative descriptions of responses where dose related effects were seen):*

Fetal data with dose level *(with NOAEL value). (Provide at a minimum qualitative descriptions of responses where dose related effects were seen:*.
Statistical results, as appropriate:

Remarks *(Describe additional information that may be needed to adequately assess data for reliability. Include the following when there are dose related effects, if available):*

Maternal data, provide at a minimum qualitative descriptions of responses where dose related effects were seen:

- *Mortality and day of death:*
- *Number pregnant per dose level:*
- *Number aborting:*
- *Number of resorptions, early/late if available:*
- *Number of implantations:*
- *Pre and post implantation loss, if available; Number of corpora lutea (recommended):*
- *Duration of Pregnancy:*
- *Body weight:*
- *Food/water consumption:*
- *Description, severity, time of onset and duration of clinical signs:*
- *Haematological findings incidence and severity:*
- *Clinical biochemistry findings incidence and severity:*
- *Gross pathology incidence and severity:*
- *Organ weight changes, particularly effects on total uterine weight:*
- *Histopathology incidence and severity:*
- *Fetal data, provide at a minimum qualitative descriptions of responses where dose related effects* were seen:

    - *Litter size and weights:*
    - *Number viable (number alive and number dead):*
    - *Sex ratio:*
    - *Postnatal growth (depending on protocol):*
    - *Postnatal survival (depending on protocol):*
    - *Grossly visible abnormalities, external, soft tissue and skeletal abnormalities :*

Conclusion

Remarks *(Identify source of comment, i.e. author and/or submitter):*

Reliability

(Data reliability code, e.g. Klimisch code, if used, possibly a flag for 'key study')

Remarks: *(The rationale for the reliability code should be described clearly as should the process by which the "Reliability" decision was made)*

References *(Free Text)*

Other

Last changed: *(administrative field for updating)*
Order number for sorting: *(administrative field)*

Remarks *(Use for any other comments necessary for clarification.)*

5.10 Other Relevant Information

5.10.A Neurotoxicity

This is not a SIDS element. When data are available, they should be reported. Relevant Test Guidelines are **OECD Test Guideline 418: 'Delayed Neurotoxicity of Organophosphorous Substances Following Acute Exposure'**; **OECD Test Guideline 419: 'Delayed Neurotoxicity of Organophosphorous Substances: 28-Day Repeated Dose Study'** and **OECD Test Guideline 424: 'Neurotoxicity Study in Rodents'**

A robust study summary template is outlined below.

Field Name	Brief Instructions
Test Substance Identity	Chemical Name and CAS # and EINECS #
Test Substance Remarks	Purity of material tested, noting impurities and their concentrations.
Method	Note specific OECD, EPA, ASTM, or other method. Please indicate if deviations from a standard method are noted. Describe deviations.
GLP	Yes/No
Year	Year study performed
Test Conditions	
Species	Name species used
Strain	Name strain used
Source	
Gender	Males, females or both
Rearing conditions	Describe rearing conditions, especially mobility of the test animals.
Age/weight at study initiation	
Number of animals per group/gender/dose	Give number per treatment and vehicle group
Control animals	Yes/No
Positive controls included	Yes/No
	Indicate identity of reference substance
Route of Administration	oral by gavage or other
Exposure	Single dose, administration once daily for 28 days or other

Field Name	Brief Instructions
Dose Levels	Note the values of the doses/concentrations and unit
Vehicle	e.g. water, gelatine capsules give justification, if not water
Concentration in vehicle	
Total volume applied	
Postexposure period	14 days or other
Anticholinergic substances used	Specify substance used for protecting test animals against acute cholinergic effects, if applicable, state concentration [mg/kg b.w.]
Controls	Vehicle or other
Body Weight	weighing before application and after application in weekly intervals
Organ Weights	Indicate whether organs weights were determined and for which organs.

Field Name	Brief Instructions
Signs of Toxicity	Clinical signs: Neuropathology Motor Activity OPIDN Behaviour abnormalities with special respect to ▪ Ataxia (measured on a scale with at least four levels) ▪ Paralysis ▪ effects observed in a period of forced motor activity (such as ladder climbing) in the animals selected for pathology. Behavioural and functional abnormalities with special respect to sensory, motor, cognitive and autonomic functions: ▪ Clinical signs/cage side/daily. ▪ Detailed clinical observation/standard arena outside cage/once before first exposure and at different time intervals thereafter. ▪ Functional tests including sensory reactivity to stimuli of different modalities (e.g. auditory, visual and proprioceptive stimuli, assessment of limb grip strength and assessment of motor activity.
Observation schedule	acute exposure: several times during the first two days and thereafter at least once daily or other repeated dose: daily observation until 14 days after the last dose or other
Clinical Chemistry	Yes/No Number of animals: All animals or other Time points: 24h and 48h (test and control group) / 24h (positive control group) after dosing recommended

Field Name	Brief Instructions	
	Parameters:	NTE (Neuropathy Target Esterase) activity in brain lumbar spinal cord sciatic nerve (optional) AChE (Acetylcholine Esterase) activity in these tissues (optional) or other
Pathology	Yes/No	
	Organs:	brain and spinal cord or other
Histopathology	Yes/No	
	Organs:	Indicate sections of the central and peripheral nervous system which were examined (e.g. forebrain, centre of the cerebrum, including a section through the hippocampus, the midbrain, the cerebellum, the pons, the medulla oblongata, the eye with optic nerve and retina, the spinal cord at the cervical and lumbar swellings, the dorsal root ganglia, the dorsal and ventral root fibres, the proximal sciatic nerve, the proximal tibia nerve and the tibial nerve calf muscle branches. Indicate whether the spinal cord and peripheral nerve sections include both cross or transverse and longitudinal sections.)
Results		
Body Weight	No effects / describe significant effects referring to data in results table	
Organ weights	No effects / describe significant effects referring to data in results table	

Field Name	Brief Instructions
Clinical signs of toxicity	No effects/describe significant effects referring to data in results table. State time of onset, type, severity, duration and reversibility of: Toxic response data (including mortality and clinical signs of toxicity). A description of all neurobehavioral findings from detailed clinical observations A description of all functional test results. Report information on reversibility of effects.
Clinical Chemistry	No effects / describe significant effects referring to data in results table
Pathology	No effects / describe significant effects referring to data in results table
Histopathology	No effects / describe significant effects referring to data in results table
Other	Statistical Methods Describe any other significant effects on: Specialised neuropathology methods (teased nerve fibre preparation, transmission electron microscopy, morphometry and immunohistochemistry). Neuroelectrophysiology, neurochemistry, neuroimmunology, and neuroendocrinology.
LOAEL	give critical effect and specific measured value
NOAEL	Give critical effect and specific measured value
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example "Klimisch" code). Present a rationale for the reliability code. In the case of deficiencies, discuss their impact and implications on the results. If relevant, justify the acceptability of the study
Reference	Present full citation of the study summarised
Remarks	Use for any other comments necessary for clarification

5.10.B Other

This section may be used to include other data that may be relevant to the complete initial hazard assessment of the test substance. The following information should be reported for each additional data element.

A. Specific Toxicities

Test Substance

Identity

Remarks

Method

Type: *(e.g. Neurotoxicity, Immunotoxicity, etc.)*

Results

Remarks

Reference

5.11 *Experience with Human Exposure

Experience with Human Exposure, if available, is a **SIDS element**. Information on workplace exposure such as concentration of chemicals in the workplace (manufacturing, maintenance and professional use) and indoor environment should be described. Information related to the number of workers (in ranges for each situation including manufacturing, maintenance and professional use), the frequency, duration and level of exposure should also be mentioned if available. In addition, details of effects of accidental or occupational exposure, epidemiological and clinical studies, case reports and the like can also be described. If data on experience with human exposure is available, it should be presented in the same order as data with laboratory animals in the previous sections.

There is no agreed Robust Study Summary template for Experience with Human Exposure, however there is a Robust Study Summary template for Epidemiology, which is presented below:.

This template is provided as an example only. Fields relevant to a particular study should be chosen when reporting exposure information.

Field Name	Brief Instructions
Test Substance	Chemical name and CAS# and EINECS#
Test Substance Remarks	Purity of material evaluated, noting impurities and their concentrations.
Manufacturing/Processing/Use Information	Provide any pertinent information on manufacturing, processing, or use of the chemical, if occupational study.
Study design	Cohort (retrospective, prospective); Case-control (retrospective, prospective); Descriptive/Correlation/Ecologic; Case report; Biological marker study; Biological monitoring study; Other
Hypothesis tested	If applicable, state the hypothesis(es) tested in this study (would not be applicable in biological monitoring study, case reports, descriptive studies).
Study Period	Dates during which the data were collected (from _to_).
Setting	Indicate the setting where this study took place, e.g., occupational, residential, hospital-based, clinical practice, environmental (e.g., fenceline of waste sites, air monitoring); its geographic location(s); and any other pertinent information.
Total population	Total number of persons in cohort from which the subjects were drawn.
Subject selection criteria	Criteria used to include and/or exclude subjects from the study.
Total number of subjects in study	Report the number of subjects participating in the study.
Comparison population	Indicate state, regional or national registries, control or reference group, other comparison group, etc. Note the parameters that were “matched” (i.e., smoking, age, sex, etc.)

Participation rate	If available, report participation rate in the study
Subject description	Include all descriptive information (and number within groups) available such as sex, age, race, SES, demographic information, exposure categories, etc.
Tables describing study population	Include tables that describe the study population
Health effects studied	List all health effects studied. Note latency period(s) for effects studied and whether the study timelines are sufficient. Also, for certain study types (i.e., prospective studies), note whether the diagnosis of the effects were made blind to exposure status.
Data collection methods	List all that apply: questionnaire; biological samples; environmental samples; work histories; record review; clinical tests (e.g., pulmonary function tests), etc.
Details on data collection	Include method of collection and analysis, method of administration and analysis, frequency of collection/administration, location of environmental samples taken (e.g,. Provide details on how questionnaire was administered or death certificates obtained, methods and other information on how environmental or biological samples were collected and analyzed, etc.).
Exposure period	Describe when subjects were exposed and duration of exposure (with units): hours, days, weeks, months, years, person-years, etc.
Description/delineation of exposure groups/categories	Identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.
Measured or estimated exposure data	Indicate whether the exposures are measured or estimated and how this was done (e.g., personal samples, ambient air sampling, etc.).
Exposure levels	Cite exposure level(s) reported (with units).
Exposure tables	Insert any exposure tables
Other descriptive information about the study	Provide any additional information here.
Statistical methods	Describe all statistical methods used and the data to which they were applied (include sample size and power calculations, if available).
Results	Describe results - include statistical results (including p values and specified confidence intervals, when available); measures of disease frequency (e.g., SMRs, ORs, PMRs, RR, prevalence, incidence, adjusted and/or crude rates, etc.); correlations; distributions, etc.
Tables	Attach tables that describe results

Other tables	Attach any other pertinent data tables
Study strengths and weaknesses	Include any possible confounders, bias, validity issues, reliability issues (including the adequacy of the exposure estimation or measurements), representativeness concerns, unique nature of study, influence of past exposures, turnover rates in occupational studies, etc..
Research sponsor(s)	List all research sponsors
Consistency of results	Discuss how these results compare with results from other studies and provide references of those studies.
Conclusions	Note the study author's conclusions and whether the submitter agrees
Reliability	Note the reliability of the study (for example, "Klimisch" code). Present a narrative clarifying the rationale for the reliability code.
Reference	Present full citation of the study summarised.
General Remarks	Use for any other comments necessary for clarification.

6. REFERENCES

Indicate the name of the book, journal etc. where the study appears; volume; page numbers; and date of report or publication. In general, information should be taken from primary sources, and quoting from secondary references, such as a review article, should be avoided. Where appropriate, indicate "unpublished report", its authors and their affiliation.

Annex 1a : List of Industry Categories

As described in section 2.2.2, the use pattern of a substance in the Sponsor country is a SIDS element. Among other information, as required in Item 1.6 of Annex 1, the industrial branch in which the substance is used should be described. The Industry categories (IC) described below can be used for that purpose.

1. Agricultural industry

Agricultural industry deals with the activities of growing crops (vegetables, grains, etc.) and raising cattle (for dairy products, meat and wool). It also comprises all allied activities such as pest control (application of pesticides, veterinary medicines), manuring, etc.

2. Chemical industry: basic chemicals

There are two different ICs for chemical industry, the industry where substances are produced through chemical reactions. The raw materials for chemical industry come from petrochemical industry (IC 9 'Mineral oil and fuel industry'), from plant or animal materials, or coal. IC 2 is dedicated to *basic chemical*s, which are substances used generally throughout all branches of chemical industry and usually in considerable amounts. Important basic chemicals are solvents (UC 48) and pH-regulating agents (UC 40) (acids, alkalis).

3. Chemical industry: chemicals used in synthesis

Chemicals used in synthesis are substances either regulating the chemical reaction process (e.g. catalysts) or being used as an intermediate (i.e. chemicals that are formed and can be isolated at an intermediate step between starting material and the final product in a sequence of chemical processes).

4. Electrical/electronic industry

In electrical/electronic industry production of a wide range of products is manufactured. It comprises both the manufacture of components like resistors, transistors, capacitors, diodes, lamps, etc. and the production of televisions, radios, computers (PC's as well as mainframes), radar installations, complete telephone exchanges, etc. In the manufacturing processes constituent processes may take place. The main constituent processes are electroplating, polymer processing, and paint application.

5. Personal/domestic

In this IC the use and application of substances in household for maintenance and care of houses, furniture, kitchenware, gardens, etc., and personal care (hygiene, make-up, etc.) is covered. Chemicals used in this IC in many cases will be present in formulations, e.g. in cleaners (soaps, detergents, washing powders, etc.), cosmetics, and products for the care of leather, textile and cars.

6. Public domain

This IC covers application and use of substances in a variety of places by skilled workers, such as offices, public buildings, waiting rooms, various workshops like garages, professional cleaning and maintenance of buildings, streets, parks, etc. Also in this IC most chemicals will be present in formulations, e.g. in "cleaners" (UC = 9 'Cleaning and washing agents and disinfectants'), non-agricultural biocides (UC = 39 'Biocides, non-agricultural'), and products for the maintenance of roads, buildings, etc.

7. Leather processing industry

Leather processing industry is considered as the industries where leather is made out of raw hides, leather is dyed and where products are made out of leather (e.g. shoe manufacture).

8. Metal extraction, refining and processing industry

This IC covers the extraction of metals from the ores, the manufacture of primary/secondary steel and non-ferro metals (as well “pure” metals as alloys), and the manifold of metal working processes (“shaping”) like cutting, drilling, rolling, etc.

9. Mineral oil and fuel industry

Mineral oil and fuel industry involves the so-called *petrochemical* industry, which processes crude mineral oil. By means of physical and chemical processes (e.g. separation by means of distillation, cracking and platforming) they produce a wide range of hydrocarbons serving as raw materials for chemical industry and (often after adding a series of additives) fuels for heating and combustion engines.

10. Photographic industry

Photographic industry is the industry where photographic materials are manufactured (“solid” materials like films and photographic “papers”, but also preparations - either in a solid or a liquid form - for film and paper processing baths. Also the processing of films and photographic paper is accounted to photographic industry, including professional processing in so-called printshops.

11. Polymers industry

Polymers industry comprises the branch of chemical industry where ‘plastics’ (thermoplastics) are chemically produced and industries where processing of thermoplastics and prepolymers takes place by means of a wide range of techniques.

12. Pulp, paper and board industry

Production of pulp, paper and cardboard out of wood or waste paper belongs to this IC, but also chemicals used in reprographic industry.

13. Textile processing industry

This IC covers treatment of fibres (“cleaning”, spinning, dyeing, etc.), weaving, and finishing (e.g. impregnation, coating, etc.).

14. Paints, lacquers and varnishes industry

Apart from the manufacture of coating products (stage of formulation) like paints this IC also covers application of these products.

16. Engineering industry: civil and mechanical

To this IC industrial activities belong such as wood processing industries (e.g. wooden

furniture), motor car manufacture, building industry, etc.

0. Others

All processes and activities, which can not be placed in one of the previous ICs, belong to this IC. An example is food processing industry.

Annex 1b: List of Use Categories

As described in section 2.2.2 of Chapter 2, the use pattern of a substance in the Sponsor country is a SIDS element. Among other information, as required in Item 1.6 of Annex 1, the function of the substance used should be described. The Use Categories (UC) described below (left column), as they are proposed by IUCLID can be used for that purpose. The corresponding functions as proposed by ChemUSES (US-EPA, 1980) are listed in the right column. A list of synonyms for functions according to ChemUSES vs. IUCLID Use category No is also presented below.

No.	USE CATEGORY (IUCLID)	No.	Function (ChemUSES)
1	Absorbents and adsorbents	131	Absorbents
		60	Adsorbents
		213	Dehumidifiers
2	Adhesive, binding agents	302	Adhesives
		143	Binders
		92	Spreaders
		165	Stickers
		280	Tackifiers
3	Aerosol propellants	178	Aerosol propellants
4	Anti-condensation agents		
5	Anti-freezing agents	77	Antifreezes
		74	De-icers
		52	Deodorants
		313	Functional fluids
6	Anti-set-off and anti-adhesive agents	104	Abherents
		63	Antiblocking agents
		188	Anticaking agents
		300	Detackifiers
		233	Dusting agents
		144	Parting agents
		7	Soil retardants
7	Anti-static agents	328	Antistatic agents
		89	Electroconductive coating agents
		318	Humectants
8	Bleaching agents	304	Bleaching assistants
		132	Bleaching agents
9	Cleaning/washing agents and additives	293	Antiredeposition agents
		180	Boil-off assistants
		242	Cleaners
		173	Detergents
		78	Pre-spotting agents
		274	Scouring agents
		261	Shrinkage controllers
		14	Soaping-off assistants
		294	Soil release agents
10	Colouring agents	5	Bloom agents
		86	Colouring agents
		174	Coupling agents (dyes)

		267	Dyes
		20	Fluorescent agents
10	Colouring agents (continued)	248	Lakes
		381	Luminescent agents
		235	Mercerising assistants
		128	Opacifiers
		139	Pearlizing agents
		125	Pigments
		83	Stains
11	Complexing agents	177	Antiprecipitants
		124	Complexing agents
		10	Sequestering agents
12	Conductive agents	161	Electrical conductive agents
		383	Electrode materials
		245	Electrolytes
		313	Functional fluids
13	Construction materials and additives	324	Case-hardening agents
		355	Concrete additives
		361	Embrittlement inhibitors
		375	Materials for shaping
		250	Reinforcing agents
		349	Water-reducing agents
14	Corrosion inhibitors	230	Antioxidants
		64	Antiscaling agents
		323	Corrosion inhibitors
15	Cosmetics	301	Antiperspirants
		167	Cosmetic ingredients
16	Dust binding agents	26	Dust control agents
17	Electroplating agents	353	Brighteners
		32	Fume suppressants
18	Explosives	179	Detonators
		363	Explosion inhibitors
		158	Explosives
		27	Incendiaries
19	Fertilisers	34	Fertilisers
20	Fillers	351	Fillers (augmentation)
		212	Fillers (patching)
		371	Surface coating additives
		127	Swelling agents
		58	Weighting agents (textile technology)
21	Fixing agents	291	Anticrock agents
		347	Antistripping agents
		268	Barrier coating agents
		295	Fixatives
		134	Fixing agents (fragrances)
		112	Fixing agents (textile technology)
		227	Mordents

22	Flame retardants and fire preventing agents	25	Fire extinguishing agents
		332	Flame retardants
23	Flotation agents	163	Activators (ore processing)
		190	Flocculating agents
		297	Flotation agents
		360	Modifiers
24	Flux agents for casting		
25	Foaming agents	358	Blowing agents
		133	Chemical blowing agents
		94	Frothers
		50	Physical blowing agents
26	Food/feedstuff additives	214	Acidulants
		66	Feed additives
		145	Food additives
		80	Sweeteners (taste)
27	Fuels	247	Fuels
28	Fuel additives	329	Antifouling agents
		76	Antiknock agents
		183	Deposit modifiers
		306	Fuel additives
		138	Sweeteners (petroleum technology)
29	Heat transferring agents	72	Coolants
		313	Functional fluids
		199	Heat transfer agents
		216	Quenchers
		208	Refrigerants
30	Hydraulic fluids and additives	313	Functional fluids
		65	Hydraulic fluids
		256	Transmission fluids
31	Impregnation agents	102	Delustrants
		98	Sizes
		258	Water repellents
		23	Waterproofing agents
32	Insulating materials	254	Acoustical insulating material
		311	Electrical insulating material
		314	Heat insulating materials
		162	Insulating materials
33	Intermediates	146	Inorganic intermediates
		115	Monomers
		290	Organic intermediates
		43	Prepolymers
34	Laboratory chemicals	238	Analytical and product testing
		122	Chelating agents
		107	Deionisers
		373	Extraction agents
		69	Indicators
		325	Oxidation-reduction indicators
		374	Reagents

35	Lubricants and additives	119	Antiseize agents
		313	Functional fluids
		148	Internal lubricating agents
		195	Lubricant additives
		364	Lubricating agents
		346	Oiliness agents
		249	Penetrants
		312	Slip agents
36	Odour agents	79	Flavours and fragrances
		339	Odorants
37	Oxidising agents	149	Oxidisers
38	Plant protection products, agricultural	166	Animal repellents
		333	Bactericides
		108	Biocides
		97	Decontaminats
		270	Fumigants
		362	Fungicides
		275	Herbicides
		155	Insect attractants
		348	Insect repellents
		330	Insecticides
		252	Nematocides
		253	Pesticides
		264	Rodenticides
39	Biocides, non-agricultural	287	Algicides
		1	Antifouling agents
		140	Disinfectants
		118	Preservatives
		116	Slime preventatives
40	pH-regulating agents	172	Laundry sours
		266	pH control agents
		191	pH indicators
41	Pharmaceuticals		
42	Photochemicals	122	Chelating agents
		198	Desensitisers (explosives)
		299	Desensitisers (photography)
		182	Developers
		286	Intensifiers (photography)
		285	Light stabilisers
		344	Photosensitive agents
		303	Sensitisers
43	Process regulators	321	Accelerators
		46	Activators (chemical processes)
		239	Activators (enzymes)
		110	Adhesion promoters
		4	Antifelting agents
		352	Antislip finishing agents
		206	Antistaining agents
		194	Antiwebbing agents
		281	Builders
		222	Carbonising agents

		164	Carriers
43	Process regulators (continued)	19	Catalyst supports
		170	Catalysts
		31	Chain extenders
		113	Chain terminators
		141	Chain transfer agents
		122	Chelating agents
		114	Coagulants
		278	Coalescents
		357	Coalescing agents
		315	Crabbing assistants
		228	Crosslinking agents
		226	Curing agents (concrete)
		369	Curing agents (polymer technology)
		18	Currying agents
		236	Deasphalting agents
		342	Defoamers
		365	Degumming agents
		137	Dehairing agents
		73	Dehydrating agents
		366	De-inkers
		84	Delignification agents
		30	Depolymerisation agents
		367	Depressants
		292	Desising agents
		259	Dispersants
		317	Dryers
		150	Dye carriers
		255	Dye levelling agents
		307	Dye retardants
		211	Dye retention aids
		341	Enzyme inhibitors
		157	Enzymes
		284	Finishing agents
		337	Formation aids
		331	Fuel oxidisers
		117	Fulling agents
		103	Initiators
		359	Intensifiers (printing)
		171	Kier boiling assistants
		24	Nucleating agents
		96	Peptising agents
		75	Pitch control agents
		121	Polymerisation additives
		209	Polymerisation inhibitors
		21	Prevulcanisation inhibitors
		153	Refining agents
		223	Repulping aids
		136	Retarders
		296	Retention aids
		338	Rubber compounding agents
		51	Scavengers
		326	Solubilising agents
		310	Weighting agents (petroleum technology)
44	Reducing agents	244	Reducers
45	Reprographic agents	225	Toners

46	Semiconductors	202	Semiconductors
		378	Photovoltaic agents
47	Softeners	269	Bates
		231	Devulcanising agents
		28	Elasticisers
		265	Emollients
		185	Plasticisers
		29	Softeners
		147	Water softeners
48	Solvents	229	Degreasers
		82	Dewaxing solvents
		373	Extraction agents
		320	Paint and varnish removers
		16	Reaction media
		271	Solvents
49	Stabilisers	277	Anticracking agents
		12	Antifume agents
49	Stabilisers (continued)	129	Antihydrolysis agents
		168	Antiozonants
		230	Antioxidants
		120	Antilivering agents
		282	Antiplasticisers
		160	Antisagging agents
		68	Antisettling agents
		88	Bloom inhibitors
		123	Coupling agents (polymers)
		159	Emulsifiers
		87	Heat stabilisers
		54	Stabilisers
		36	Ultraviolet absorbers
50	Surface-active agents	41	Antifloating agents
		234	Antifogging agents
		109	Surfactants
		243	Wetting agents
51	Tanning agents	316	Tanning agents
52	Viscosity adjustors	152	Antiflooding agents
		120	Antilivering agents
		343	Antiskinning agents
		221	Gelling agents
		262	Pour point depressants
		272	Thickeners
		334	Thixotropic agents
		240	Turbulence suppressors
		135	Viscosity adjustors
		15	Viscosity index improvers
53	Vulcanising agents	288	Vulcanising agents
54	Welding and soldering agents	101	Brazing agents
		22	Fluxing agents

0 Other

204 Ablatives
105 Abrasives
196 Activators (luminescence)
354 Aerating agents
47 Air entraining agents
376 Alloying agents
90 Anticratering agents
48 Anticreasing agents
99 Antifogging agents
218 Antipilling agents
350 Antiskid agents
6 Blasting abrasives
70 Bluing agents
220 Bright dips
93 Chemical raw materials
298 Clarifiers
260 Cloud point depressants
130 Coating agents
283 Collectors
335 Coupling agents (solutions)
215 Culture nutrients
81 Deaerating agents
309 Deblooming agents
85 Dechlorinating agents
73 Dehydrating agents
107 Deionisers
232 Demulsifiers
200 Denaturants
49 Descaling agents
205 Dewatering aids
356 Discharge printing agents
38 Drainage aids
44 Drilling mud additives
322 Dry strength additives
39 Dye stripping agents
100 Electron emission agents
340 Eluting agents
372 Embalming agents
186 Encapsulating agents
57 Enhanced oil recovery agents
308 Entraining agents
319 Etching agents
336 Evaporation control agents
373 Extraction agents
207 Fiber-forming compounds
368 Filtration aids
56 Flatting agents
79 Flavours and fragrances
142 Fluid loss additives
313 Functional fluids
193 Greaseproofing agents
184 "Grinding, lapping, sanding and"
192 Hormones
246 Humidity indicators
210 Hydrotropic agents
181 Impact modifiers
380 Incandescent agents
69 Indicators
2 Ion exchange agents

91 Lachrymators
33 Latex compounding agents
53 Leaching agents
156 Leather processing agents
370 Liquid crystals
381 Luminescent agents
379 Magnetic agents
67 Mar proofing agents
289 Metal conditioners
95 Metal strippers
37 Metal treating agents
327 Milling aids
237 Obscuring agents
197 Oil repellents
62 Optical quenchers
382 Osmotic membranes
17 Papermaking agents
55 Phosphatising agents
203 Phosphorescent agents
59 Pickling agents
217 Pickling inhibitors
251 Plant growth regulators
176 Plastics additives
224 Plastics for shaping
169 Plating agents
8 Poison gas decontaminants
3 Polymer strippers
111 Pore forming agents
151 Precipitating agents
106 Protective agents
45 Radioactivity decontaminants
374 Reagents
219 Refractive index modifiers
241 Refractories
154 Resists
9 Rinse aids
71 Ripening agents
187 Rubber for shaping
201 Rubber reclaiming agents
189 Rubbing fastness agents
276 Rust inhibitors
11 Rust removers
263 Scrooping agents
42 Sealants
98 Sizes
126 Slime control agents
305 Soil conditioners
61 Strippers
40 Tar removers
345 Tarnish inhibitors
13 Tarnish removers
279 Textile specialities
257 Vat printing assistants
273 Wax strippers
35 Well treating agents
175 Wet strength additives
377 X-ray absorbents

List of synonyms for functions according to ChemUSES (US-EPA, 1980) vs. IUCLID Use category No.

No.	ChemUSES Function	Use category IUCLID (No.)
104	Abherents	6
204	Ablatives	55
105	Abrasives	0
131	Absorbents	1
321	Accelerators	43
214	Acidulants	26
254	Acoustical insulating material	32
46	Activators (chemical processes)	43
163	Activators (ore processing)	23
196	Activators (luminescence)	55
239	Activators (enzymes)	43
110	Adhesion promoters	43
302	Adhesives	2
60	Adsorbents	1
354	Aerating agents	0
178	Aerosol propellents	3
47	Air entraining agents	0
287	Algicides39	
376	Alloying agents	0
238	Analytical and product testing	34
166	Animal repellents	38
63	Antiblocking agents	6
188	Anticaking agents	6
277	Anticracking agents	49
90	Anticratering agents	0
48	Anticreasing agents	0
291	Anticrock agents	21
4	Antifelting agents	43
41	Antifloating agents	50
152	Antiflooding agents	52
234	Antifogging agents	50
99	Antifogging agents	0
1	Antifouling agents	39
329	Antifouling agents	28
77	Antifreezes	5
12	Antifume agents	49
129	Antihydrolysis agents	49
76	Antiknock agents	28
120	Antilivering agents	49, 52
230	Antioxidants	14, 49
168	Antiozonants	49
301	Antiperspirants	15
218	Antipilling agents	55
282	Antiplasticisers	49
177	Antiprecipitants	11
293	Antiredeposition agents	9
160	Antisagging agents	49
64	Antiscaling agents	14
119	Antiseize agents	35
68	Antisettling agents	49
350	Antiskid agents	0
343	Antiskinning agents	52
352	Antislip finishing agents	43
206	Antistaining agents	43
328	Antistatic agents	7
347	Antistripping agents	21
194	Antiwebbing agents	43
333	Bactericides	38
268	Barrier coating agents	21
269	Bates	47
143	Binders	2
108	Biocides 38	
6	Blasting abrasives	0
132	Bleaching agents	8
304	Bleaching assistants	8
5	Bloom agents	10
88	Bloom inhibitors	49
358	Blowing agents	25
70	Bluing agents	0
180	Boil-off assistants	9
101	Brazing agents	54
220	Bright dips	0
353	Brighteners	17
281	Builders	43
222	Carbonising agents	43
164	Carriers	43
324	Case-hardening agents	13
170	Catalysts	43
19	Catalyst supports	43
31	Chain extenders	43
113	Chain terminators	43
141	Chain transfer agents	43
122	Chelating agents	34, 42, 43
133	Chemical blowing agents	25
93	Chemical raw materials	0
298	Clarifiers	0
242	Cleaners	9
260	Cloud point depressants	0
114	Coagulants	43
278	Coalescents	43
357	Coalescing agents	43
130	Coating agents	0
283	Collectors	0
86	Colouring agents	10
124	Complexing agents	11
355	Concrete additives	13
72	Coolants	29
323	Corrosion inhibitors	14
167	Cosmetic ingredients	15
123	Coupling agents (polymers)	49
174	Coupling agents (dyes)	10
335	Coupling agents (solutions)	55
315	Crabbing assistants	43
228	Crosslinking agents	43
215	Culture nutrients	0
226	Curing agents (concrete)	43
369	Curing agents (polymer technology)	43
18	Currying agents	43
366	De-inkers	43
81	Deaerating agents	0
236	Deasphalting agents	43
309	Deblooming agents	0
85	Dechlorinating agents	55
97	Decontaminats	38
342	Defoamers	43
229	Degreasers	48
365	Degumming agents	43
137	Dehairing agents	43
213	Dehumidifiers	1
73	Dehydrating agents	0, 34
74	Deicers	5
107	Deionizers	0, 34

84 Delignification agents 43
102 Delustrants 31
232 Demulsifiers 0
200 Denaturants 0
52 Deodorants 5
30 Depolymerisation agents 43
183 Deposit modifiers 28
367 Depressants 43
49 Descaling agents 0
198 Desensitisers (explosives) 42
299 Desensitisers (photography) 42
292 Desizing agents 43
300 Detackifiers 6
173 Detergents 9
179 Detonators 18
182 Developers 42
231 Devulcanising agents 47
205 Dewatering aids 0
82 Dewaxing solvents 48
356 Discharge printing agents 0
140 Disinfectants 39
259 Dispersants 43
38 Drainage aids 0
317 Dryers 43
44 Drilling mud additives 0
322 Dry strength additives 0
26 Dust control agents 16
233 Dusting agents 6
150 Dye carriers 43
255 Dye leveling agents 43
307 Dye retardants 43
211 Dye retention aids 43
39 Dye stripping agents 0
267 Dyes 10
28 Elasticisers 47
161 Electrical conductive agents 12
311 Electrical insulating material 32
89 Electroconductive coating agents 7
383 Electrode materials 12
245 Electrolytes 12
100 Electron emission agents 0
340 Eluting agents 0
372 Embalming agents 0
361 Embrittlement inhibitors 13
265 Emollients 47
159 Emulsifiers 49
186 Encapsulating agents 0
57 Enhanced oil recovery agents 0
308 Entraining agents 0
341 Enzyme inhibitors 43
157 Enzymes 43
319 Etching agents 0
336 Evaporation control agents 0
363 Explosion inhibitors 18
158 Explosives 18
373 Extraction agents 34, 48
66 Feed additives 26
34 Fertilisers 19
207 Fiber-forming compounds 0
212 Fillers (patching) 20
351 Fillers (augmentation) 20
368 Filtration aids 0
284 Finishing agents 43
25 Fire extinguishing agents 22
295 Fixatives 21
112 Fixing agents (textile technology) 21
134 Fixing agents (fragrances) 21
332 Flame retardants 22
56 Flatting agents 0
79 Flavours and fragrances 0, 36
190 Flocculating agents 23
297 Flotation agents 23
142 Fluid loss additives 0
20 Fluorescent agents 10
22 Fluxing agents 54
145 Food additives 26
337 Formation aids 43
94 Frothers 25
306 Fuel additives 28
331 Fuel oxidisers 43
247 Fuels 27
117 Fulling agents 43
32 Fume suppressants 17
270 Fumigants 38
313 Functional fluids 0, 5, 12, 29, 30, 35
362 Fungicides 38
221 Gelling agents 52
193 Greaseproofing agents 0
184 Grinding, lapping, sanding and polishing abrasives 0
199 Heat transfer agents 29
314 Heat insulating materials 32
87 Heat stabilisers 49
275 Herbicides 38
192 Hormones 0
318 Humectants 7
246 Humidity indicators 0
65 Hydraulic fluids 30
210 Hydrotropic agents 0
181 Impact modifiers 0
380 Incandescent agents 0
27 Incendiaries 18
69 Indicators 0, 34
103 Initiators 43
146 Inorganic intermediates 33
155 Insect attractants 38
348 Insect repellents 38
330 Insecticides 38
162 Insulating materials 32
286 Intensifiers (photography) 42
359 Intensifiers (printing) 43
148 Internal lubricating agents 35
2 Ion exchange agents 0
171 Kier boiling assistants 43
91 Lachrymators 0
248 Lakes 10
33 Latex compounding agents 0
172 Laundry sours 40
53 Leaching agents 0
156 Leather processing agents 0
285 Light stabilisers 42
370 Liquid crystals 0
195 Lubricant additives 35
364 Lubricating agents 35
381 Luminescent agents 0, 10
379 Magnetic agents 0
67 Mar proofing agents 55
375 Materials for shaping 13
235 Mercerising assistants 10
289 Metal conditioners 0
37 Metal treating agents 0
95 Metal strippers 0
327 Milling aids 0
360 Modifiers 23

115	Monomers	33
227	Mordents	21
252	Nematocides	38
24	Nucleating agents	43
237	Obscuring agents	0
339	Odorants	36
197	Oil repellents	0
346	Oiliness agents	35
128	Opacifiers	10
62	Optical quenchers	0
290	Organic intermediates	33
382	Osmotic membranes	0
325	Oxidation-reduction indicators	34
149	Oxidisers	37
320	Paint and varnish removers	48
17	Papermaking agents	0
144	Parting agents	6
139	Pearlising agents	10
249	Penetrants	35
96	Peptising agents	43
253	Pesticides	38
191	pH indicators	40
266	pH control agents	40
55	Phosphatising agents	0
203	Phosphorescent agents	0
344	Photosensitive agents	42
378	Photovoltaic agents	42
50	Physical blowing agents	25
217	Pickling inhibitors	0
59	Pickling agents	0
125	Pigments	10
75	Pitch control agents	43
251	Plant growth regulators	0
185	Plasticisers	47
176	Plastics additives	0
224	Plastics for shaping	0
169	Plating agents	0
8	Poison gas decontaminants	0
3	Polymer strippers	0
121	Polymerisation additives	43
209	Polymerisation inhibitors	43
111	Pore forming agents	0
262	Pour point depressants	52
78	Pre-spotting agents	9
151	Precipitating agents	0
43	Prepolymers	33
118	Preservatives	39
21	Prevulcanisation inhibitors	43
106	Protective agents	0
216	Quenchers	29
45	Radioactivity decontaminants	0
16	Reaction media	48
374	Reagents	0, 34
244	Reducers	44
153	Refining agents	43
219	Refractive index modifiers	0
241	Refractories	0
208	Refrigerants	29
250	Reinforcing agents	13
223	Repulping aids	43
154	Resists	0
136	Retarders	43
296	Retention aids	43
9	Rinse aids	0
71	Ripening agents	0
264	Rodenticides	38
338	Rubber compounding agents	43
187	Rubber for shaping	0
201	Rubber reclaiming agents	0
189	Rubbing fastness agents	0
11	Rust removers	0
276	Rust inhibitors	0
51	Scavengers	43
274	Scouring agents	9
263	Scrooping agents	0
42	Sealants	0
202	Semiconductors	46
303	Sensitisers	42
10	Sequestering agents	11
261	Shrinkage controllers	9
98	Sizes	0, 31
126	Slime control agents	0
116	Slime preventatives	39
312	Slip agents	35
14	Soaping-off assistants	9
29	Softeners	47
305	Soil conditioners	0
294	Soil release agents	9
7	Soil retardants	6
326	Solubilising agents	43
271	Solvents	48
92	Spreaders	2
54	Stabilisers	49
83	Stains	10
165	Stickers	2
61	Strippers	0
371	Surface coating additives	20
109	Surfactants	50
138	Sweeteners (petroleum technology)	28
80	Sweeteners (taste)	26
127	Swelling agents	20
280	Tackifiers	2
316	Tanning agents	51
40	Tar removers	0
13	Tarnish removers	0
345	Tarnish inhibitors	0
279	Textile specialities	0
272	Thickeners	52
334	Thixotropic agents	52
225	Toners	45
256	Transmission fluids	30
240	Turbulence suppressors	52
36	Ultraviolet absorbers	49
257	Vat printing assistants	0
135	Viscosity adjustors	52
15	Viscosity index improvers	52
288	Vulcanising agents	53
147	Water softeners	47
258	Water repellents	31
349	Water-reducing agents	13
23	Waterproofing agents	31
273	Wax strippers	0
310	Weighting agents (petroleum technology)	43
58	Weighting agents (textile technology)	20
35	Well treating agents	0
175	Wet strength additives	0
243	Wetting agents	50
377	X-ray absorbents	0