

REVISED OECD HPV FORM 1

SIDS DOSSIER ON THE HPV PHASE CHEMICAL

.....

CAS No.-...-

Sponsor Country :

DATE:

ALSO AVAILABLE: ANNEX 2 MODEL SIDS DOSSIER

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Note: *; Data elements in the SIDS

†; Data elements specially required for inorganic chemicals

SIDS PROFILE

DATE:

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ISSUES FOR DISCUSSION (IDENTIFY, IF ANY)	SIDS testing required:	

SIDS SUMMARY

DATE:

CAS NO:		Information	OECD Study	GLP	Other Study	Estimation Method	Acceptable	SIDS Testing Required
STUDY		Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYSICAL-CHEMICAL DATA								
2.1	Melting Point							
2.2	Boiling Point							
2.3	Density							
2.4	Vapour Pressure							
2.5	Partition Coefficient							
2.6	Water Solubility							
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	· Chromosomal aberration							
5.6	Genetic Toxicity <i>in vivo</i>							
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5.9	Development / Teratogenicity							
5.11	Human experience							
OTHER TOXICITY STUDIES RECEIVED								

1. **GENERAL INFORMATION**

1.01 **SUBSTANCE INFORMATION**

- *A. Cast number
- B. Name (*IUPAC name*)
- *C. Name (*OECD name*)
- †D. CAS Descriptor (*where applicable for complex chemicals*)
.....
- E. EINECS-Number
- F. Molecular Formula
- G. Structural Formula (*indicate the structural formula in smiles code, if available*)
.....
- H. Substance Group (*if possible, only for petroleum products, see HEDSET explanatory note*)
.....
- I. Substance Remark (*Indicate the substance remark as prescribed in the EINECS Inventory, if possible*)
.....
- J. Molecular Weight

1.02 **OECD INFORMATION**

- A. Sponsor Country:
- B. Lead Organisation:
Name of Lead Organisation:.....
Contact person:
Address:
Street:
Postal code:
Town:
Country:
Tel:
Fax:

C. **Name of responder** *(Information on a responder should be provided when companies respond to Lead Organisation or SIDS Contact Points.)*

Name:
Address:
 Street:
 Postal code:
 Town:
 Country:
 Tel:
 Fax:

1.1 GENERAL SUBSTANCE INFORMATION

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 SYNONYMS

1.3 IMPURITIES [Indicate CAS No., chemical name (IUPAC name is preferable), percentage, if possible EINECS number.]

CAS No:
EINECS No:
Name:
Value:
Remarks:

1.4 ADDITIVES (e.g. stabilising agents, inhibitors etc. Indicate CAS No., chemical name (IUPAC name is preferable), percentage, if possible EINECS number), the component of the UVCB (substance with no defined composition) should be indicated here.)

CAS No:
EINECS No:
Name:
Value:
Remarks:

***1.5 QUANTITY [Information on production or import levels should be provided in figures or ranges (e.g. 1,000-5,000, 5,000-10,000 tonnes, etc.) per responder or country and the date for which those ranges apply should be given. For EU Member states, only indicate the EU import figure. Give an estimation of the global production quantity in the remarks field. Information on the number of producers in the country and the source of information should also be given in the remarks field.]**

Remarks: (If possible, indicate if the substance was produced and/or imported during the 12 months following adoption of the EU regulation on existing chemicals.)

Reference:

1.6 LABELLING AND CLASSIFICATION *[If possible, enter information on labelling and classification, such as labelling and classification system, existence of specific limit, symbols, nota, R-Phrases and S-Phrases of EC Directive 67/548/EEC. See HEDSET Explanatory Note.]*

Labelling

Type:
Specific limits:
Symbols:
Nota:
R-phrases:
S-phrases:
Text of S-phrases:
Remarks:

Classification

Type:
Category of danger:
R-phrases:
Remarks:

***1.7 USE PATTERN**

A. General *[Data on use pattern have to be given by assigning main types according to their exposure relevance (i.e. non-dispersive use, use in closed systems, use resulting in inclusion into or onto matrix and wide dispersive use), industrial categories (e.g. basic chemical industry, chemical industry, agricultural industry, personal and domestic use) and use categories such as colouring agents, intermediates, solvents, adhesives, cleaning/washing agents, fertilisers, impregnation agents, surface-active, etc. If available, give an estimation of different uses in percentage terms.]*

	Type of Use:	Category:
	(a) main	
	industrial	
	use	
	(b) main	
	industrial	
	use	
Remarks:	(a)	
		
	(b)	
		
Reference:		

- B. **Uses in Consumer Products** [If the chemical is present in consumer products as marketed, give details of products' function (e.g. detergent, etc.), and percentage in product and physical state of product as marketed (e.g. aerosol, powder or liquid)]

<u>Function</u>	<u>Amount present</u>	<u>Physical state</u>
.....		

Remarks:
Reference:

- 1.8 **OCCUPATIONAL EXPOSURE LIMIT VALUE** (Indicate the type of occupational exposure limit value including short-term exposure limit value. If a value does not exist, give the hygiene standard of the producer company if available. See also 5.11.)

Exposure limit value

Type:
Value:

Short term exposure limit value

Value:
Length of exposure period:.....
Frequency:
Remarks:
Reference:

* 1.9 **SOURCES OF EXPOSURE**

Describe sources of potential human [other than concentration of chemicals in the workplace and indoor environment (see 5.11)], or environmental exposure, including emission data (e.g. quantities per media with information such as time dimensions of release, indication of type of release (e.g. point source or diffuse), type of estimating (e.g. average or worst case), uncertainties in estimation), for all phases of the life cycle of the chemical, if available, including manufacturing and user areas.

For environmental exposure, indicate the production process briefly, number of sites of manufacture and, the basis for concluding that the process is "closed" if applicable.

Also an indication of measured exposure levels (expressed in an appropriate form, e.g. geometric mean and standard deviation) can be mentioned here. Any information that will help to focus the assessment of exposure (either quantitative or qualitative in nature) can be mentioned, if available.)

Source: Media of release:
Quantities per media:.....
Remarks:
Reference:

1.10 ADDITIONAL REMARKS

A. Options for disposal *[Mode of disposal (e.g. incineration, release to sewage system, etc.) for each category and type of use, if appropriate; recycling possibility]*

Remarks:
Reference:

B. Other remarks

Remarks:
Reference:

2. PHYSICAL-CHEMICAL DATA

***2.1 MELTING POINT** *(If more than one, identify the recommended value.)*

Value:°C
Decomposition: Yes ☐ No ☐ Ambiguous ☐
Sublimation: Yes ☐ No ☐ Ambiguous ☐
Method: *[e.g. OECD, other (with the year of publication or updated of the method used)]*
.....
GLP: Yes ☐ No ☐ ? ☐
Remarks:
Reference:

***2.2 BOILING POINT** *(If more than one, identify the recommended value.)*

Value:°C
Pressure: at hPa
Decomposition: Yes ☐ No ☐ Ambiguous ☐
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes ☐ No ☐ ? ☐
Remarks:
Reference:

†2.3 DENSITY (relative density) *(Where applicable, indicate the relative density of the substance.)*

Type: Bulk density ☐; Density ☐; Relative Density ☐
Value:
Temperature:°C
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes ☐ No ☐ ? ☐
Remarks:
Reference:

***2.4 VAPOUR PRESSURE** *(if more than one, identify the recommended value)*

Value: hPa
 Temperature: °C
 Method: calculated []; measured []
[e.g. OECD, other (with the year of publication or updated of the method used)].

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

***2.5 PARTITION COEFFICIENT $\log_{10} P_{ow}$ (if more than one, identify the recommended value)**

Log Pow:
 Temperature: °C
 Method: calculated []; measured []
[e.g. OECD, other (with the year of publication or updating of the method used)].

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

***2.6 WATER SOLUBILITY (if more than one, identify the recommended value)**

A. Solubility

Value:
 Temperature: °C
 Description: Miscible []; Of very high solubility [];
 Of high solubility []; Soluble []; Slightly soluble [];
 Of low solubility []; Of very low solubility []; Not soluble []
 Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

B. pH Value, pKa Value

pH Value:
 Concentration:
 Temperature: °C
 Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*

 GLP: Yes [] No [] ? []
(Where applicable, enter values for the dissociation constant(s) and the conditions under which they were measured.)
 pKa value at 25°C
 Remarks:
 Reference:

2.7 FLASH POINT (liquids)

Value: °C
 Type of test: Closed cup []; Open cup []; Other []
 Method: (with the year of publication or updating of the method used)

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

2.8 AUTO FLAMMABILITY (solid/gases)

Value: °C
 Pressure: hPa
 Method: (with the year of publication or updating of the method used)

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

2.9 FLAMMABILITY

Results: Extremely flammable []; Extremely flammable - liquified gas [];
 Highly Flammable []; Flammable []; Non flammable [];
 Spontaneously flammable in air []; Contact with water liberates highly
 flammable gases []; Other []
 Method: (with the year of publication or updating of the method used)

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

2.10 EXPLOSIVE PROPERTIES

Results: Explosive under influence of a flame [];
 More sensitive to friction than m-dinitrobenzene [];
 More sensitive to shock than m-dinitrobenzene []; Not explosive [];
 Other []
 Method: (with the year of publication or updating of the method used)

 GLP: Yes [] No [] ? []
 Remarks:
 Reference:

2.11 OXIDISING PROPERTIES

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

Method: (with the year of publication or updating of the method used).....
.....

GLP: Yes [] No [] ? []

Remarks:

Reference:

†2.12 OXIDATION: REDUCTION POTENTIAL

(Where applicable, indicate the redox potential and the conditions under which it was measured.)

Value: mV

Method: (with the year of publication or updating of the method used)
.....

GLP: Yes [] No [] ? []

Remarks:

Reference:

2.13 ADDITIONAL DATA

A. Partition co-efficient between soil/sediment and water (K_d)

Value:

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

GLP: Yes [] No [] ? []

Remarks:

Reference:

B. Other data

(e.g. Henry's Law constant, fat solubility, surface tension (of aqueous solution), adsorption/desorption on soil, particle size distribution, etc.)

Results:

Remarks:

Reference:

3. **ENVIRONMENTAL FATE AND PATHWAYS**

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

3.1 **STABILITY**

*3.1.1 **PHOTODEGRADATION**

Type: Air ☐; Water ☐; Soil ☐; Other ☐
Light source: Sunlight ☐; Xenon lamp ☐; Other ☐
Light spectrum: nm
Relative intensity: (based on intensity of sunlight)
Spectrum of substance: [e.g. λ (max.) (>295nm) and ϵ (max) or ϵ (295nm)]
..... nm
Concentration of Substance:
Temperature: °C
Direct photolysis:
Half life:
Degradation: % (weight/weight) after (exposure time)
Quantum yield:
Indirect Photolysis:
Type of sensitizer:
Concentration of sensitizer:
Rate constant (radical): cm²/molecule*sec
Degradation:
Method: calculated ☐; measured ☐
[e.g. OECD, other (with the year of publication or updating of the method used)]
.....
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks:
Reference:

*3.1.2 **STABILITY IN WATER**

Type: Abiotic (hydrolysis) ☐; biotic (sediment) ☐
Half life: at pH at °C
Degradation: at pH at °C after
..... (exposure time)
Method: [e.g. OECD, other (with the year of publication or updating of the method used)]
.....
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks: (e.g. CAS number, name and percentage of degradation products)
.....
Reference:

3.1.3 STABILITY IN SOIL

Type : Field trial ☐; Laboratory ☐; Other ☐
Radiolabel: Yes ☐ No ☐ ? ☐
Concentration:
Soil temperature: °C
Soil humidity:
Soil classification: DIN19863 ☐; NF X31-107 ☐; USDA ☐; Other ☐
year
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)
Method: [e.g. OECD, other (with the year of publication or updating of the method used)]
.....
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks:
Reference:

*3.2 MONITORING DATA (ENVIRONMENTAL)

Note that data on biological effects monitoring, including biomagnification, and biotransformation and kinetics in environmental species are to be reported in section 4.7 and 4.8, respectively. Nonetheless, concentration in various biota should be reported here. Data on concentration in the workplace or indoor environment should be reported under item 5.11.

Type of Measurement: Background ☐; At contaminated site ☐; Other ☐
Media:
Results:
Remarks:
Reference:

3.3 TRANSPORT AND DISTRIBUTION BETWEEN ENVIRONMENTAL COMPARTMENTS INCLUDING ESTIMATED ENVIRONMENTAL CONCENTRATIONS AND DISTRIBUTION PATHWAYS (e.g. during the chemical life-cycle. The information 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.)

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*3.3.1 TRANSPORT

Type: Adsorption []; Desorption []; Volatility []; Other []
Media:
Method:
Results:
Remarks:
Reference:

*3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)

Media: Air-biota []; Air-biota-sediment-soil-water []; Soil-biota [];
Water-air []; Water-biota []; Water-soil []; Other []
Method: Fugacity level I []; Fugacity level II []; Fugacity level III []; Fugacity
level IV []; Other (calculation) []; Other (measurement) []
Results:
Remarks:
Reference:

3.4 IDENTIFICATION OF MAIN MODE OF DEGRADABILITY IN ACTUAL USE

Results:
Remarks:
Reference:

*3.5 BIODEGRADATION

Type: aerobic []; anaerobic []
Inoculum: adapted []; non-adapted [];
Concentration of the chemical: related to COD []; DOC []; test substance []
Medium: water []; water-sediment []; soil []; sewage treatment []
Degradation: (percentage reduction/exposure time)
..... % after (time)
Results: (see OECD Guidelines) readily biodeg. []; inherently biodeg. [];
under test condition no biodegradation observed [], other []
Kinetic (e.g. Zahn-Wellens-Test) % in (time)
Method: [e.g. OECD, other (with the year of publication or updating of the
method used)].
.....
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks: [In the case of poorly soluble chemicals, treatment given (nature,
concentration, CAS number, name and percentage of degradation
products etc.)]:
.....
Reference:

3.6 BOD₅, COD OR RATIO BOD₅/COD

BOD₅

Method:
Concentration: related to COD []; DOC []; Test substance []
Value: mg O₂/l
GLP: Yes [] No [] ? []

COD

Method:
Value: mg O₂/g
GLP: Yes [] No [] ? []

Ratio BOD₅/COD:

Remarks:
Reference:

3.7 BIOACCUMULATION

Species:
Exposure period:
Temperature: °C
Concentration:
BCF:
Elimination: Yes [] No [] ? []
Method: [e.g. OECD, other (with the year of publication or updating of the method used)].

Type of test: calculated []; measured []
static []; semi-static []; flow-through []; other (e.g. field test) []
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

3.8 ADDITIONAL REMARKS

A. Sewage treatment (information on treatability of the substance)

Results:
Remarks:
Reference:

B. Other information [information that will help to focus the exposure assessment (either qualitative or quantitative)]

Results:
Remarks:
Reference:

4. **ECOTOXICITY**

*4.1 **ACUTE/PROLONGED TOXICITY TO FISH**

Type of test: static ☐; semi-static ☐; flow-through ☐; other (*e.g. field test*) ☐
open-system ☐; closed-system ☐

Species:

Exposure period:

Results: LC_{50} (24h) = mg/l
 LC_{50} (48h) = mg/l
 LC_{50} (72h) = mg/l
 LC_{50} (96h) = mg/l
NOEC = mg/l
LOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

4.2 **ACUTE TOXICITY TO AQUATIC INVERTEBRATES**

*A. **Daphnia**

Type of test: static ☐; semi-static ☐; flow-through ☐; other (*e.g. field test*) ☐
open-system ☐; closed-system ☐

Species:

Exposure period:

Results: EC_{50} (24h) = mg/l
 EC_{50} (48h) = mg/l
 EC_{50} (.h) = mg/l
NOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

B. **Other aquatic organisms**

Type of test: static ☐; semi-static ☐; flow-through ☐; other (*e.g. field test*) ☐
open-system ☐; closed-system ☐

Species:

Exposure period:

Results: EC₅₀ (24h) = mg/l
 EC₅₀ (48h) = mg/l
 EC₅₀ (.h) = mg/l
 NOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

 GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

*4.3 TOXICITY TO AQUATIC PLANTS, e.g. algae

Species:

Endpoint: Biomass ☐; Growth rate ☐; Other ☐

Exposure period:

Results: EC₅₀ (..... h) = mg/l
 (Endpoint) EC₅₀ (..... h) = mg/l
 NOEC = mg/l
 LOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

 open-system ☐; closed-system ☐

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

4.4 TOXICITY TO BACTERIA (Single species tests and tests on overall processes such as nitrification or soil respiration are included in this item.)

Type: Aquatic ☐; Field ☐; Soil ☐; Other ☐

Species:

Exposure Period:

Results: EC₅₀ (... h) = mg/l
 EC₅₀ (... h) = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1 CHRONIC TOXICITY TO FISH (effects on reproduction, embryo/larva, etc.)

Type of test: static ☐ ; semi-static ☐ ; flow-through ☐ ; other (e.g. field test) ☐ ;
open-system ☐ ; closed-system ☐

Species:

Endpoint: Length of fish ☐ ; Weight of fish ☐ ;
Reproduction rate ☐ ; Other ☐

Exposure period:

Results: EC₅₀ (..d) = mg/l
(Endpoint) EC₅₀ (..d) = mg/l
NOEC = mg/l
LOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

(*)4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES (e.g. daphnia reproduction. The need to conduct tests for this endpoint will depend inter alia upon possible concern for long term effects.)

Type of test: static ☐ ; semi-static ☐ ; flow-through ☐ ; other (e.g. field test) ☐ ;
open-system ☐ ; closed-system ☐

Species:

Endpoint: Mortality ☐ ; Reproduction rate ☐ ; Other ☐

Exposure period:

Results: EC₅₀ (..... h) = mg/l
(Endpoint) EC₅₀ (..... d) = mg/l
NOEC = mg/l
LOEC = mg/l

Analytical monitoring: Yes ☐ No ☐ ? ☐

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

Type : Artificial soil ☐ ; Filter paper ☐ ; Other ☐

Species:

Endpoint: Mortality ☐ ; Weight ☐ ; Other ☐

Exposure period:

Results: EC_{50} (.....d) = mg/kg
(Endpoint) EC_{50} (.....d) = mg/kg
 EC_{xx} (.....d) = mg/kg
NOEC = mg/kg
LOEC = mg/kg

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

(a)

Species:

Endpoint: Emergence ☐ ; Growth ☐ ; Other ☐

Exposure period:

Results: EC_{50} and/or LC_{50} (7d) = mg/l
 EC_{50} and/or LC_{50} (14d) = mg/l
 EC_{xx} and/or LC_{xx} (xxd) = mg/l
NOEC = mg/l
LOEC = mg/l

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

GLP: Yes ☐ No ☐ ? ☐

Test substance:, purity:

Remarks:

Reference:

(b)

Species:

Endpoint: Emergence ☐ ; Growth ☐ ; Other ☐

Exposure period:

Results: EC_{50} and/or LC_{50} (7d) = mg/l
 EC_{50} and/or LC_{50} (14d) = mg/l
 EC_{xx} and/or LC_{xx} (xxd) = mg/l
NOEC = mg/l
LOEC = mg/l

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

GLP: Yes [] No [] ? []
 Test substance: , purity:
 Remarks:
 Reference:

(c)
 Species:
 Endpoint: Emergence []; Growth []; Other []
 Exposure period:
 Results: EC₅₀ and/or LC₅₀ (7d) = mg/l
 EC₅₀ and/or LC₅₀ (14d) = mg/l
 EC_{xx} and/or LC_{xx} (xxd) = mg/l
 NOEC = mg/l
 LOEC = mg/l
 Method: [e.g. OECD, other (with the year of publication or updating of the method used)]

GLP: Yes [] No [] ? []
 Test substance: , purity:
 Remarks:
 Reference:

4.6.3 TOXICITY TO OTHER NON MAMMALIAN TERRESTRIAL SPECIES (INCLUDING AVIAN)

Species:
 Endpoint: Mortality []; Reproduction rate []; Weight []; Other []
 Exposure period:
 Results: LD₅₀ or LC₅₀ (xxd) = mg/kg
 NOEC = mg/kg
 LOEC = mg/kg
 Method: [e.g. OECD, other (with the year of publication or updating of the method used)]

GLP: Yes [] No [] ? []
 Test substance: , purity:
 Remarks:
 Reference:

4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION) (Studies on variation of predominant species in certain ecosystems (e.g. mesocosm) and monitoring of biological effects are included.)

Results: Substance:
 Species or ecosystem studied:
 Effects monitored:
 Results:
 Chemical analysis:

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

Reference:

4.8 BIOTRANSFORMATION AND KINETICS

(Under this item, studies on absorption, distribution, metabolism and excretion etc. should be given.)

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

Results:

Remarks:

Reference:

4.9 ADDITIONAL REMARKS

Results:

Remarks:

Reference:

5. **TOXICITY**

(Where observations on humans are available, these should be entered in the appropriate "Comments" section or under section 5.11.)

*5.1 **ACUTE TOXICITY**

5.1.1 **ACUTE ORAL TOXICITY**

Type: LD₀ []; LD₁₀₀ []; LD₅₀ []; LD_L []; Other []
Species/strain:
Value: mg/kg b.w.:
Discriminating dose:
Method: [e.g. OECD, other (with the year of publication or updating of the method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.1.2 **ACUTE INHALATION TOXICITY**

Type: LC₀ []; LC₁₀₀ []; LC₅₀ []; LCL₀ []; Other []
Species/strain:
Exposure time:
Value:
Method: [e.g. OECD, other (with the year of publication or updating of the method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.1.3 **ACUTE DERMAL TOXICITY**

Type: LD₀ []; LD₁₀₀ []; LD₅₀ []; LD_L []; Other []
Species/strain:
Value: mg/kg b.w.
Method: [e.g. OECD, other (with the year of publication or updating of the method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION

(e.g. subcutaneous, intravenous, etc.)

Type: LC₀ [] ; LC₁₀₀ [] ; LC₅₀ [] ; LCL₀ [] ; Other []
LD₀ [] ; LD₁₀₀ [] ; LD₅₀ [] ; LDL₀ [] ; Other []
Species/strain:
Route of Administration: i.m. [] ; i.p. [] ; i.v. [] ; infusion [] ; s.c. [] ; other []
Exposure time:
Value:
Method: [e.g. OECD, other (with the year of publication or updating of the
method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

Species/strain:
Results: Highly corrosive [] ; Corrosive [] ; Highly irritating [] ;
Irritating [] ; Moderate irritating [] ; Slightly irritating [] ;
Not irritating []
Classification: (If possible, according to EC Directive 67/548/EEC)
Highly corrosive (causes severe burns) [] ;
Corrosive (causes burns) [] ; Irritating [] ; Not irritating []
Method: [e.g. OECD, other (with the year of publication or updating of the
method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.2.2 EYE IRRITATION/CORROSION

Species/strain:
Results: Highly corrosive [] ; Corrosive [] ; Highly irritating [] ;
Irritating [] ; Moderate irritating [] ; Slightly irritating [] ;
Not irritating []
Classification: (if possible, according to EC Directive 67/548/EEC)
Irritating [] ; Not irritating [] ; Risk of serious damage to eyes []
Method: [e.g. OECD, other (with the year of publication or updating of the
method used)]
GLP: Yes [] No [] ? []
Test substance:, purity:
Remarks:
Reference:

5.3 SKIN SENSITISATION

Type:
 Species/strain:
 Results: Sensitizing []; Not sensitizing []; Ambiguous []
 Classification: (if possible, according to EC Directive 67/548/EEC)
 Sensitizing []; Not sensitizing []
 Method: [e.g. OECD, other (with the year of publication or updating of the
 method used)]
 GLP: Yes [] No [] ? []
 Test substance:, purity:
 Remarks:
 Reference:

*5.4 REPEATED DOSE TOXICITY

Species/strain:
 Sex: Female []; Male []; Male/Female []; No data []
 Route of Administration:
 Exposure period:
 Frequency of treatment:
 Post exposure observation period:
 Dose:
 Control group: Yes []; No []; No data [];
 Concurrent no treatment []; Concurrent vehicle []; Historical []
 NOEL:
 LOEL:
 Results:
 Method: [e.g. OECD, other (with the year of publication or updating of the
 method used)]
 GLP: Yes [] No [] ? []
 Test substance:, purity:
 Reference:

*5.5 GENETIC TOXICITY IN VITRO

A. BACTERIAL TEST

Type: (e.g. Bacterial reverse mutation assay, Bacterial gene mutation study,
 Cytogenetic Assay etc.)
 System of testing:
 Concentration:
 Metabolic activation: With []; Without []; With and Without []; No data []
 Results:
 Cytotoxicity conc: With metabolic activation:
 Without metabolic activation:
 Precipitation conc:
 Genotoxic effects: + ? -

Reference:

5.7 CARCINOGENICITY

Species/strain:
Sex: Female ☐ ; Male ☐ ; Male/Female ☐ ; No data ☐
Route of Administration:
Exposure period:
Frequency of treatment:
Postexposure observation period:
Doses:
Control group: Yes ☐ ; No ☐ ; No data ☐ ;
Concurrent no treatment ☐ ; Concurrent vehicle ☐ ; Historical ☐
Results:
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks:
Reference:

*5.8 TOXICITY TO REPRODUCTION

Type: Fertility ☐ ; One-generation study ☐ ; Two-generation study ☐ ;
Other ☐
Species/strain:
Sex: Female ☐ ; Male ☐ ; Male/Female ☐ ; No data ☐
Route of Administration:
Exposure period:
Frequency of treatment:
Post exposure observation period:
Premating exposure period: male:, female:
Duration of the test:
Doses:
Control group: Yes ☐ ; No ☐ ; No data ☐ ;
Concurrent no treatment ☐ ; Concurrent vehicle ☐ ; Historical ☐
NOEL Parental:
NOEL F1 Offspring:
NOEL F2 Offspring:
Results:
General parental toxicity:
Toxicity to offspring: *(weights of litter, postnatal growth, viability, etc.)*
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks:

Reference:

*5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

Species/strain:
Sex: Female ☐ ; Male ☐ ; Male/Female ☐ ; No data ☐
Route of Administration:
Duration of the test:
Exposure period:
Frequency of treatment:
Doses:
Control group: Yes ☐ ; No ☐ ; No data ☐ ;
Concurrent no treatment ☐ ; Concurrent vehicle ☐ ; Historical ☐
NOEL Maternal Toxicity:
NOEL teratogenicity :
Results:
Maternal general toxicity:
Pregnancy/litter data:
Foetal data:
Method: [e.g. OECD, other (with the year of publication or updating of the
method used)]
GLP: Yes ☐ No ☐ ? ☐
Test substance:, purity:
Remarks:
Reference:

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

Type: (e.g. neurotoxicity, immunotoxicity, etc.)
Results:
Remarks:
Reference:

B. Toxicodynamics, toxicokinetics

Type: (e.g. toxicodynamics, toxicokinetics)
Results:
Remarks:
References:

* 5.11 EXPERIENCE WITH HUMAN EXPOSURE

(Describe information on workplace exposure such as concentration of chemicals in the workplace or indoor environment (manufacturing, maintenance and professional use), number of workers (in ranges for each situation), frequency and duration of exposure, if available. In

addition, enter details of effects of accidental or occupational exposure, epidemiological and clinical studies, case reports, etc.)

Results:
Remarks:
Reference:

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.)