

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Oxytetracycline / Diclofenac Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.2	19.05.2025	1313899-00023	Date of first issue: 20.02.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Oxytetracycline / Diclofenac Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A	H360FD: May damage fertility. May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word : Danger

Hazard statements :
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :
Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

oxytetracycline
Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
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	EC-No. Index-No. Registration number		(% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD specific concentra- tion limit Repr. 1B; H360FD > 3 %	>= 30 - < 50
oxytetracycline	79-57-2 201-212-8	Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 20 - < 25
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 Acute toxicity esti- mate Acute oral toxicity: 1.200 mg/kg	>= 1 - < 10
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6 239-346-4	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Gastrointestinal tract, Blood, lym- phatic system, Liv- er, Prostate) Aquatic Chronic 2; H411	>= 0,25 - < 1
Sodium hydroxymethanesulphonate	149-44-0 205-739-4	Muta. 2; H341 Repr. 2; H361d EUH032	>= 0,1 - < 1

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- | | | |
|----------------------------|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| If inhaled | : | If inhaled, remove to fresh air.
Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | May cause an allergic skin reaction.
Causes serious eye irritation.
May damage fertility. May damage the unborn child. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
|------------------------------|---|--|

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Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

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Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
oxytetracycline	79-57-2	TWA	500 µg/m3 (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 µg/100 cm ²	Internal
Magnesium oxide	1309-48-4	TWA (Dust)	10 mg/m3	FOR-2011-12-06-1358
Sodium [2-[(2,6-dichloro-phe-nyl)amino]phenyl]a cetate	15307-79-6	TWA	60 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	6000 µg/100cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef-fects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef-fects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17,1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef-fects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5,2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef-fects	33,3 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic ef-fects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef-fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3

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	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day
Sodium hy- droxymethanesulphi- nate	Workers	Inhalation	Long-term systemic effects	21 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	140 mg/m3
	Workers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Workers	Skin contact	Acute local effects	0,225 mg/cm2

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
oxytetracycline	Fresh water	0,0003 mg/l
	Marine water	0,0003 mg/l
2-Pyrrolidone	Fresh water	0,5 mg/l
	Freshwater - intermittent	0,5 mg/l
	Marine water	0,05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0,4205 mg/kg dry weight (d.w.)
	Soil	0,0612 mg/kg dry weight (d.w.)
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
Sodium hydroxymethanesulphi- nate	Soil	0,456 mg/kg
	Fresh water	0,056 mg/l
	Marine water	0,006 mg/l
	Freshwater - intermittent	0,056 mg/l
	Sewage treatment plant	1 mg/l
	Fresh water sediment	0,046 mg/kg dry weight (d.w.)
	Marine sediment	0,005 mg/kg dry weight (d.w.)
	Soil	0,011 mg/kg dry

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		weight (d.w.)
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8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	light brown
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available

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range

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 8,3 - 9,0
(as aqueous solution)

Viscosity
Viscosity, kinematic : 47,62 mm²/s

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

Density : 1,05 - 1,18 g/cm³

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

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Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Method: OECD Test Guideline 402

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Assessment: The substance or mixture has no acute dermal toxicity

oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4.800 mg/kg
LD50 (Mouse): 2.240 mg/kg
Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 4.840 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 3.500 mg/kg
Application Route: Subcutaneous

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous
LD50 (Mouse): 92 - 147 mg/kg
Application Route: Intravenous

Sodium hydroxymethanesulphonate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal

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toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

2-Pyrrolidone:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

oxytetracycline:

Remarks	:	No data available
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Benzyl alcohol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result	:	irritating
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Sodium hydroxymethanesulphinate:

Species	:	Rat
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Pyrrolidone:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 7 days

oxytetracycline:

Remarks	:	No data available
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Benzyl alcohol:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result	:	Mild eye irritation
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Sodium hydroxymethanesulphinate:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative
Remarks	:	Based on data from similar materials

oxytetracycline:

Test Type	:	Human repeat insult patch test (HRIPT)
Result	:	Sensitiser

Benzyl alcohol:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans
Result	:	positive

Assessment	:	Probability or evidence of low to moderate skin sensitisation rate in humans
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Sodium hydroxymethanesulphinate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Germ cell mutagenicity

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Components:

2-Pyrrolidone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative

oxytetracycline:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Result: negative Test Type: Mouse Lymphoma Metabolic activation: Metabolic activation Result: positive Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: equivocal Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: equivocal Test Type: in vivo assay Species: Mouse Application Route: Intraperitoneal injection Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

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Benzyl alcohol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: CHO Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
		Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: positive
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: positive
Germ cell mutagenicity- Assessment	:	Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	18 month(s)
Result	:	negative

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Remarks : Based on data from similar materials

oxytetracycline:

Species : Mouse
Application Route : Oral
Exposure time : 104 weeks
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 103 weeks
Result : equivocal
Target Organs : Adrenal gland, Pituitary gland
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

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Effects on foetal develop-
ment

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

Reproductive toxicity - As-
sessment

: Clear evidence of adverse effects on sexual function and fertil-
ity, based on animal experiments., Clear evidence of adverse
effects on development, based on animal experiments.

oxytetracycline:

Effects on fertility

: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Result: No effects on fertility, No effect on reproduction capac-
ity, No significant adverse effects were reported

Effects on foetal develop-
ment

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1.500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2.100 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 41,5 mg/kg body weight
Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20,75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

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Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 5 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

Sodium hydroxymethanesulphinat:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

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Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs	: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment	: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species	: Rat
NOAEL	: 207 mg/kg
Application Route	: Ingestion
Exposure time	: 3 Months
Method	: OECD Test Guideline 408

oxytetracycline:

Species	: Rat
LOAEL	: 198 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Target Organs	: Bone
Remarks	: No significant adverse effects were reported

Species	: Mouse
LOAEL	: 7.990 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Target Organs	: Bone
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 125 mg/kg
LOAEL	: 250 mg/kg
Application Route	: Oral
Exposure time	: 12 Months
Target Organs	: Testis
Remarks	: Significant toxicity observed in testing

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Species	: Rat
NOAEL	: 40 mg/kg
LOAEL	: 100 mg/kg
Application Route	: Intraperitoneal
Exposure time	: 14 Days
Target Organs	: Kidney

Benzyl alcohol:

Species	: Rat
NOAEL	: 1,072 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species	: Rat
LOAEL	: 0,25 mg/kg
Application Route	: Oral
Exposure time	: 98 w
Target Organs	: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species	: Dog
LOAEL	: 1 mg/kg
Application Route	: Oral
Exposure time	: 12 w
Target Organs	: Blood

Species	: Baboon
NOAEL	: 0,5 mg/kg
LOAEL	: 5 mg/kg
Application Route	: Oral
Exposure time	: 52 w
Target Organs	: Gastrointestinal tract, Blood
Symptoms	: constipation, Diarrhoea

Sodium hydroxymethanesulphinate:

Species	: Rat
NOAEL	: 600 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks
Method	: OECD Test Guideline 408

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

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Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

oxytetracycline:

Ingestion : Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50 : > 1.000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

oxytetracycline:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 621 mg/l

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aquatic invertebrates		Exposure time: 48 h Method: OECD Test Guideline 202
		EC50 (Moina macrocopa (Water flea)): 126,7 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena): 0,032 mg/l Exposure time: 72 h
		NOEC (Anabaena): 0,0031 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 (activated sludge): 17,9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC (activated sludge): 0,2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	:	10
Benzyl alcohol:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 80,1 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9
plants mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2
mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox- : NOEC: 0,32 mg/l
icity) Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other : NOEC: 10 mg/l
aquatic invertebrates (Chron- Exposure time: 21 d
ic toxicity) Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
plants Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC : 10 mg/l
Exposure time: 4 h

Toxicity to fish (Chronic tox- : NOEC: 13,5 mg/l
icity) Exposure time: 35 d
Species: Danio rerio (zebra fish)

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Method: OECD Test Guideline 210

Toxicity to daphnia and other : EC10: 8 mg/l
aquatic invertebrates (Chronic toxicity) : Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 77 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0,71
octanol/water : Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n- : log Pow: 1,05
octanol/water

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n- : log Pow: 4,51
octanol/water

Sodium hydroxymethanesulphinate:

Partition coefficient: n- : log Pow: < 0,3
octanol/water

12.4 Mobility in soil

No data available

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12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
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	(Oxytetracycline)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Oxytetracycline)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo)	: 964

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aircraft)
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.	
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable	
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable	
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable	
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable	
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable	
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.			
E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H301	: Toxic if swallowed.
H302	: Harmful if swallowed.
H315	: Causes skin irritation.
H317	: May cause an allergic skin reaction.
H319	: Causes serious eye irritation.
H341	: Suspected of causing genetic defects.
H360D	: May damage the unborn child.
H360FD	: May damage fertility. May damage the unborn child.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H411	: Toxic to aquatic life with long lasting effects.
EUH032	: Contact with acids liberates very toxic gas.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Irrit.	: Eye irritation
Muta.	: Germ cell mutagenicity
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	: Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of

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Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Eye Irrit. 2	H319
Skin Sens. 1	H317
Repr. 1A	H360FD
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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