

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
6.0	14.04.2025	9374267-00012	Date of first issue: 27.08.2021

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

#### 1.1 Product identifier

Trade name : Oxytetracycline (10%) Formulation

Other means of identification : ENGEMYCIN (A003308)  
COOPERS ENGEMYCIN 100 OXYTETRACYCLINE  
HYDROCHLORIDE 100MG/ML INJECTION (37256)

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

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)**

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.

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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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms :



Signal word : Danger

Hazard statements	:	H315	Causes skin irritation.
		H317	May cause an allergic skin reaction.
		H319	Causes serious eye irritation.
		H360D	May damage the unborn child.
		H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements	:	<b>Prevention:</b>	
		P201	Obtain special instructions before use.
		P264	Wash skin thoroughly after handling.
		P273	Avoid release to the environment.
		P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
		<b>Response:</b>	
		P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P391	Collect spillage.		

Hazardous components which must be listed on the label:  
oxytetracycline

### 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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Oxytetracycline	79-57-2	Skin Sens. 1A;	>= 10 - < 20

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	201-212-8	H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
Ethanolamine	141-43-5 205-483-3 603-030-00-8	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 Aquatic Chronic 3; H412  specific concentra- tion limit STOT SE 3; H335 ≥ 5 %	≥ 1 - < 2.5
Sodium hydroxymethanesulphinate	149-44-0 205-739-4	Muta. 2; H341 Repr. 2; H361d	≥ 0.1 - < 1

For explanation of abbreviations see section 16.

## 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

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

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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 (NO<sub>x</sub>)

### 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.

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### 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.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 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.  
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.

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Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
: 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

## 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/m <sup>3</sup> (OEB 2)	Internal
		Further information: DSEN		
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Ethanolamine	141-43-5	TWA	1 ppm 2.5 mg/m <sup>3</sup>	GB EH40
		Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		
		STEL	3 ppm 7.6 mg/m <sup>3</sup>	GB EH40
		Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		
		TWA	1 ppm 2.5 mg/m <sup>3</sup>	2006/15/EC

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	Further information: Indicative, Identifies the possibility of significant uptake through the skin
	STEL      3 ppm 7.6 mg/m <sup>3</sup> 2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin

### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanolamine	Workers	Inhalation	Long-term local effects	3.3 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	2 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	0.24 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	3.75 mg/kg bw/day
Sodium hydroxymethanesulphonate	Workers	Inhalation	Long-term systemic effects	21 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	140 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Workers	Skin contact	Acute local effects	0.225 mg/cm <sup>2</sup>

### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
oxytetracycline	Fresh water	0.0003 mg/l
	Marine water	0.0003 mg/l
Ethanolamine	Fresh water	0.085 mg/l
	Freshwater - intermittent	0.028 mg/l
	Marine water	0.0085 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.434 mg/kg dry weight (d.w.)
	Marine sediment	0.0434 mg/kg dry weight (d.w.)
	Soil	0.0367 mg/kg dry weight (d.w.)
Sodium hydroxymethanesulphonate	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

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		weight (d.w.)
	Marine sediment	0.005 mg/kg dry weight (d.w.)
	Soil	0.011 mg/kg dry weight (d.w.)

### 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.

Laboratory operations do not require special containment.

#### 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
Skin and body protection	:	Work uniform or laboratory coat.
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 BS 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

Appearance	:	liquid, Aqueous solution
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available



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Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Molecular weight	:	No data available
Particle size	:	Not applicable

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## 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.
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### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
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### 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 toxicological effects

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

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### 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

##### Ethanolamine:

Acute oral toxicity : LD50 (Rat): 1,089 mg/kg

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Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 mg/kg

### Sodium hydroxymethanesulphinate:

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 toxicity

### Skin corrosion/irritation

Causes skin irritation.

### Components:

#### oxytetracycline:

Remarks : No data available

#### Ethanolamine:

Species : Rabbit  
Result : Corrosive after 3 minutes to 1 hour of exposure

### Sodium hydroxymethanesulphinate:

Species : Rat  
Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### oxytetracycline:

Remarks : No data available

#### Ethanolamine:

Species : Rabbit  
Result : Irreversible effects on the eye

### Sodium hydroxymethanesulphinate:

Species : Rabbit

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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:

##### **oxytetracycline:**

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

##### **Ethanolamine:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

##### **Sodium hydroxymethanesulphonate:**

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

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **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

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		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.

### Ethanolamine:

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
		Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 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.

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### Carcinogenicity

Not classified based on available information.

### Components:

#### 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
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### Reproductive toxicity

May damage the unborn child.

### Components:

#### 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 capacity, No significant adverse effects were reported
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Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight Result: Postimplantation loss., Skeletal malformations
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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

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

### Ethanolamine:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

### Sodium hydroxymethanesulphonate:

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

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### STOT - single exposure

Not classified based on available information.

#### Components:

##### Ethanolamine:

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

Not classified based on available information.

#### Components:

##### Ethanolamine:

Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

### Repeated dose toxicity

#### Components:

##### 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

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

##### Ethanolamine:



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Species	: Rat
NOAEL	: > 120 mg/kg
Application Route	: Ingestion
Exposure time	: > 75 Days
Remarks	: Based on data from similar materials

Species	: Rat
NOAEL	: >= 0.15 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

### Sodium hydroxymethanesulphonate:

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.

### Experience with human exposure

#### Components:

#### oxytetracycline:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### 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 aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 621 mg/l 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

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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

### Ethanolamine:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 65 mg/l  
Exposure time: 48 h  
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 1.24 mg/l  
Exposure time: 41 d  
Species: Oryzias latipes (Orange-red killifish)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.85 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

### Sodium hydroxymethanesulphonate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l  
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l 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 toxicity)	:	NOEC: 13.5 mg/l Exposure time: 35 d Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10: 8 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

#### Components:

##### **Ethanolamine:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: > 90 % Exposure time: 21 d Method: OECD Test Guideline 301A
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##### **Sodium hydroxymethanesulphinate:**

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

#### Components:

##### **Ethanolamine:**

Partition coefficient: n-octanol/water	:	log Pow: -2.3 Method: OECD Test Guideline 107
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##### **Sodium hydroxymethanesulphinate:**

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Partition coefficient: n-octanol/water : log Pow: < 0.3

### 12.4 Mobility in soil

No data available

### 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 Other adverse effects

#### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

## 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

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.  
(Oxytetracycline)

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

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
<b>ADR</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
<b>RID</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
<b>IMDG</b>	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
<b>IATA (Cargo)</b>	
Packing instruction (cargo aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III

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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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)

: Conditions of restriction for the following entries should be considered:  
Number on list 3

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

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UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	not.	
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable	
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable	
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable	
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable	
Control of Major Accident Hazards Regulations 2015 (COMAH)	:		
E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### 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

H302	:	Harmful if swallowed.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H332	:	Harmful if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H360D	:	May damage the unborn child.

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H361d	:	Suspected of damaging the unborn child.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation
STOT SE	:	Specific target organ toxicity - single exposure
2006/15/EC	:	Europe. Indicative occupational exposure limit values
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
2006/15/EC / TWA	:	Limit Value - eight hours
2006/15/EC / STEL	:	Short term exposure limit
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 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



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### 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:

Skin Irrit. 2	H315
Eye Irrit. 2	H319
Skin Sens. 1	H317
Repr. 1A	H360D
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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.

GB / EN