

# SAFETY DATA SHEET



## Oxytetracycline (10%) Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 5495956-00013      Date of last issue: 07.02.2025  
Date of first issue: 10.03.2020

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### Section 1: Identification

**Product identifier** : Oxytetracycline (10%) Formulation  
**Other means of identification** : ENGEMYCIN (A003308)  
COOPERS ENGEMYCIN 100 OXYTETRACYCLINE  
HYDROCHLORIDE 100MG/ML INJECTION (37256)

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### Manufacturer or supplier's details

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

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### Section 2: Hazard identification

#### Classification of the substance or mixture

Skin corrosion/irritation : Category 2  
Serious eye damage/eye irritation : Category 2  
Skin sensitisation : Category 1  
Reproductive toxicity : Category 1A  
Short-term (acute) aquatic hazard : Category 1  
Long-term (chronic) aquatic hazard : Category 1

#### GHS Label elements, including precautionary statements

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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

: **Prevention:**

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing mist or vapours.  
P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

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Chemical name	CAS-No.	Concentration (% w/w)
oxytetracycline	79-57-2	>= 10 -< 20
Ethanolamine	141-43-5	>= 1 -< 3
Sodium hydroxymethanesulphonate	149-44-0	>= 0.1 -< 1

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### Section 4: First-aid measures

#### Description of necessary 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.

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.

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.

#### 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.

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).

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

Treatment : Treat symptomatically and supportively.

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### Section 5: Fire-fighting measures

#### Extinguishing media

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

Unsuitable extinguishing media : None known.

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### 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)

### Special protective actions for fire-fighters

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

### 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).

### 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.

### Methods and materials 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.

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### Section 7: Handling and storage

#### 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.

#### Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

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### Section 8: Exposure controls/personal protection

#### Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal

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Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Ethanolamine	141-43-5	PEL (long term)	3 ppm 7.5 mg/m <sup>3</sup>	SG OEL
		PEL (short term)	6 ppm 15 mg/m <sup>3</sup>	SG OEL
		TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH

**Appropriate engineering control 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.

### Individual protection measures, such as personal protective equipment (PPE)

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.

Skin 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 type : Combined particulates and organic vapour type

Hand protection : Chemical-resistant gloves

Material

### Section 9: 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

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Evaporation rate	:	Not applicable
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
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.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

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### Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.

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products

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**Section 11: Toxicological information**

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

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

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### **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
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#### **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
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#### **Ethanolamine:**

Species	: Rabbit
Result	: Irreversible effects on the eye

#### **Sodium hydroxymethanesulphinate:**

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

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**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 hydroxymethanesulphinate:**

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 Species: Mouse Cell type: Bone marrow Application Route: Oral

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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: negativeTest 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 hydroxymethanesulphonate:**

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negativeTest 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: positiveGerm cell mutagenicity -  
Assessment

: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

**Carcinogenicity**

Not classified based on available information.

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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

**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
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
	:	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

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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.

### STOT - single exposure

Not classified based on available information.

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**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:**

||| Species : Rat  
||| NOAEL : > 120 mg/kg

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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.

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## Section 12: Ecological information

### 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  NOEC (Anabaena): 0.0031 mg/l

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		Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10
M-Factor (Chronic 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
<b>Ethanolamine:</b>		
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 fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l Exposure time: 41 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.85 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

### Sodium hydroxymethanesulphinate:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h

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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 fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 13.5 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210

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

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

**Persistence and degradability****Components:****Ethanolamine:**

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

**Sodium hydroxymethanesulphinate:**

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

**Bioaccumulative potential****Components:****Ethanolamine:**

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

**Sodium hydroxymethanesulphinate:**

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

# SAFETY DATA SHEET



## Oxytetracycline (10%) Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 5495956-00013      Date of last issue: 07.02.2025  
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### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

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## Section 13: Disposal considerations

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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.

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## Section 14: Transport information

### **International Regulations**

#### **UNRTDG**

UN number : UN 3082

UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Oxytetracycline)

Transport hazard class(es) : 9

Packing group : III

Labels : 9

Environmental hazards : yes

#### **IATA-DGR**

UN/ID No. : UN 3082

UN proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Oxytetracycline)

Transport hazard class(es) : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

#### **IMDG-Code**

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Oxytetracycline)

Transport hazard class(es) : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

# SAFETY DATA SHEET



## Oxytetracycline (10%) Formulation

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### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### 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.

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## Section 15: Regulatory information

### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## Section 16: Other information

Revision Date : 14.04.2025

### Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

# SAFETY DATA SHEET



## Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 14.04.2025	SDS Number: 5495956-00013	Date of last issue: 07.02.2025 Date of first issue: 10.03.2020
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AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN