

## Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 21.11.2023
6.0	05.12.2023	5495955-00010	Date of first issue: 10.03.2020

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### Section 1: Identification

Product name : Oxytetracycline (10%) Formulation

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

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800  
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2

Skin sensitisation : Category 1

Reproductive toxicity : Category 1


Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

#### GHS label elements

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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.  
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.
- 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

Chemical name	CAS-No.	Concentration (% w/w)
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oxytetracycline	79-57-2	>= 10 -< 20
Ethanolamine	141-43-5	>= 1 -< 2.5
Sodium hydroxymethanesulphinate	149-44-0	>= 0.1 -< 1

### Section 4: 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.  
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.
- Most important symptoms and effects, both acute and delayed : 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).
- Notes to physician : Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- 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>)
- 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

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so.  
Evacuate area.

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

Hazchem Code : 3Z

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### Section 6: Accidental release measures

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

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 : 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

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

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- 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 : 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

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	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	WES-TWA	3 ppm 7.5 mg/m <sup>3</sup>	NZ OEL
		WES-STEL	6 ppm 15 mg/m <sup>3</sup>	NZ OEL
		TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH

- 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

- 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 : Chemical-resistant gloves

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Eye 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 and body protection : Work uniform or laboratory coat.

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**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

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

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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 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 products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : 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:**

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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

**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



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**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

**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

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**Chronic toxicity****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  
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

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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:

#### **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

### Reproductive toxicity

May damage the unborn child.

### Components:

#### **oxytetracycline:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat

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- 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  
 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

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Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

**Sodium hydroxymethanesulphinate:**

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.

**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

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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  
Application Route : Ingestion  
Exposure time : > 75 Days  
Remarks : Based on data from similar materials

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

**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.

**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****Ecotoxicity****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 : EC50 (Daphnia magna (Water flea)): 621 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Anabaena): 0.032 mg/l  
plants : Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic tox- : 10  
icity)

M-Factor (Chronic aquatic : 10  
toxicity)

Toxicity to microorganisms : EC50: 17.9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 0.2 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8  
plants : mg/l

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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  
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.



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

#### Sodium hydroxymethanesulphinate:

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

#### 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  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
 N.O.S.  
 (oxytetracycline)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 Environmentally hazardous : yes

## Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 21.11.2023
6.0	05.12.2023	5495955-00010	Date of first issue: 10.03.2020

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### IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (oxytetracycline)
Class	:	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)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### NZS 5433

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	3Z
Marine pollutant	:	no

### 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/legislation specific for the substance or mixture

#### HSNO Approval Number

HSR100757 Veterinary Medicines Limited Pack Size Finished Dose Group Standard

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### HSW Controls

Certified handler certificate not required.  
 Tracking hazardous substance not required.  
 Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

### 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 : 05.12.2023

#### 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/>

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)  
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average  
 ACGIH / STEL : Short-term exposure limit  
 NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average  
 NZ OEL / WES-STEEL : Workplace Exposure Standard - Short-Term Exposure Limit

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 Con-

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centration 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.

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