

**Oxytetracycline (10%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495945-00013	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)

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Skin irritation : Category 2

Eye irritation : Category 2A

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :   

Signal Word : Danger

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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.  
 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.

**Other hazards which do not result in classification**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Oxytetracycline	79-57-2	Skin Sens., 1A Repr., 1A Aquatic Acute, 1 Aquatic Chronic, 1	>= 10 -< 20
Ethanolamine	141-43-5	Flam. Liq., 4 Acute Tox. (Oral), 4 Acute Tox. (Inhalation), 4 Acute Tox. (Dermal), 4 Skin Corr., 1B Eye Dam., 1 STOT SE, 3	>= 1 -< 2,5

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		Aquatic Acute, 2 Aquatic Chronic, 3	
Sodium hydroxymethanesulphinate	149-44-0	Muta., 2 Repr., 2	$\geq 0,1$ -< 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 method : Use extinguishing measures that are appropriate to local cir-

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ods cumstances 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.

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

**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 diking or other appropriate containment to keep material from spreading. If diked 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.

**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 vapors.  
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.
- Conditions for safe storage : Keep in properly labeled 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  
 : Self-reactive substances and mixtures  
 : Organic peroxides  
 : Explosives  
 : Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients 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	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 vapor 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : liquid, Aqueous solution

Color : No data available

Odor : No data available

Odor 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

Vapor pressure : No data available

Relative vapor 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

Autoignition 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 characteristics		
Particle size	:	Not applicable

**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.

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 40 mg/l Exposure time: 4 h Test atmosphere: vapor Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method

**Components:****Oxytetracycline:**

Acute oral toxicity	:	LD50 (Rat): 4.800 mg/kg
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	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: vapor Method: Expert judgment 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
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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

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**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 hydroxymethanesulphonate:**

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

**Respiratory or skin sensitization****Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Oxytetracycline:**

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

**Ethanolamine:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

**Sodium hydroxymethanesulphonate:**

Test Type : Maximization Test  
Routes of exposure : 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

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	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 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

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	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
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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

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

	Test Type: Embryo-fetal development
	Species: Rat
	Application Route: Oral
	General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight

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<div style="border-left: 3px double black; height: 100%;"></div>	<p>Embryo-fetal toxicity.: NOAEL: 1.500 mg/kg body weight Result: No teratogenic effects. Remarks: Maternal toxicity observed.</p> <p>Test Type: Embryo-fetal development Species: Mouse Application Route: Oral General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 2.100 mg/kg body weight Result: No teratogenic effects. Remarks: Maternal toxicity observed.</p> <p>Test Type: Embryo-fetal development Species: Rabbit Application Route: Intramuscular Embryo-fetal toxicity.: LOAEL: 41,5 mg/kg body weight Result: Postimplantation loss., No fetal abnormalities.</p> <p>Test Type: Embryo-fetal development Species: Dog Application Route: Intramuscular Embryo-fetal toxicity.: LOAEL: 20,75 mg/kg body weight Result: Skeletal and visceral variations ., Postimplantation loss.</p> <p>Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.</p>
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**Ethanolamine:**

<div style="border-left: 3px double black; height: 100%;"></div>	<p>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</p> <p>Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative</p>
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**Sodium hydroxymethanesulphinate:**

<div style="border-left: 3px double black; height: 100%;"></div>	<p>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</p> <p>Effects on fetal development : Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414</p>
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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.
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**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.
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**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

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**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 : >= 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.

**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 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 : EC50 (Anabaena): 0,032 mg/l

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plants	Exposure time: 72 h
	NOEC (Anabaena): 0,0031 mg/l
	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

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

Partition coefficient: n-octanol/water	: log Pow: -2,3 Method: OECD Test Guideline 107
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**Sodium hydroxymethanesulphinate:**

Partition coefficient: n-octanol/water	: log Pow: < 0,3
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**Mobility in soil**

No data available

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**Other adverse effects**

No data available

**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.

**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

**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.

**Domestic regulation****ANTT**

**Oxytetracycline (10%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495945-00013	Date of first issue: 10.03.2020

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
Class	:	9
Packing group	:	III
Labels	:	9
Hazard Identification Number	:	90

**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.

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 14.04.2025  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material 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.

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

ACGIH / STEL : Short-term exposure limit

**Oxytetracycline (10%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495945-00013	Date of first issue: 10.03.2020

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; TECL - 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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