

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

SECTION 1. PRODUCT AND COMPANY 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 name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2A
Skin sensitization : Category 1
Reproductive toxicity : Category 1A

GHS label elements

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.

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 vapors.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

the workplace.

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.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

If swallowed	: If easy to do, remove contact lens, if worn. Get medical attention. 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 ₂) 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 _x)
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.
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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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.
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 : 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

Oxytetracycline (10%) Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 5495953-00012 Date of last issue: 07.02.2025
 Date of first issue: 10.03.2020

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 ³ (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Ethanolamine	141-43-5	VLE-PPT	3 ppm	NOM-010-STPS-2014
		VLE-CT	6 ppm	NOM-010-STPS-2014
		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

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

Appearance : liquid, Aqueous solution

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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
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.
------------	---	--

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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

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 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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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

Ethanolamine:

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

Sodium hydroxymethanesulphinate:

Species : Rat
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Oxytetracycline:**

Remarks : No data available

Ethanolamine:

Species : Rabbit
Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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	
	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	

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

	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 hydroxymethanesulphonate:

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
---------	---------

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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 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 Embryo-fetal toxicity.: NOAEL: 1,500 mg/kg body weight Result: No teratogenic effects. Remarks: Maternal toxicity observed. 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. 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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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.

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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal 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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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
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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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 (<i>Oryzias latipes</i> (Japanese medaka)): 110 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (<i>Daphnia magna</i> (Water flea)): 621 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 EC50 (<i>Moina macrocopa</i> (Water flea)): 126.7 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (<i>Anabaena</i>): 0.032 mg/l Exposure time: 72 h NOEC (<i>Anabaena</i>): 0.0031 mg/l Exposure time: 72 h
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:

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

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 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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

II**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
--	---	----------------

Mobility in soil

No data available

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 (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

(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**NOM-002-SCT**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Oxytetracycline)

Class : 9
Packing group : III
Labels : 9

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**

Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

producing capsules, tablets and pills.

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value
PPT	:	
NOM-010-STPS-2014 / VLE-	:	Short term exposure limit value
CT	:	

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 Sub-

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
4.0	14.04.2025	5495953-00012	Date of first issue: 10.03.2020

stances 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

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.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8