

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline (10%) Formulation

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

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION**GHS Classification**

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

Hazard pictograms :   

Signal word : Danger

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

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

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.
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 2025/04/14	SDS Number: 5495950-00012	Date of last issue: 2025/02/07 Date of first issue: 2020/03/10
----------------	------------------------------	------------------------------	---

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
oxytetracycline	79-57-2	≥ 10 - < 25
Ethanolamine	141-43-5	≥ 1 - < 2.5
Sodium hydroxymethanesulphinate	149-44-0	< 1

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.

5. FIREFIGHTING 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 prod-	: Carbon oxides

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

ucts	Nitrogen oxides (NOx)
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 firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

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.

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.

Materials to avoid : Store in accordance with the particular national regulations.
Do not store with the following product types:
Strong oxidizing agents

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 ³ (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Ethanolamine	141-43-5	NAB	3 ppm	ID OEL
		PSD	6 ppm	ID 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

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.

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

Skin and body protection : Work uniform or laboratory coat.

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.

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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

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.

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: > 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

Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 2025/04/14	SDS Number: 5495950-00012	Date of last issue: 2025/02/07 Date of first issue: 2020/03/10
----------------	------------------------------	------------------------------	---

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

Components:**oxytetracycline:**

Acute oral toxicity	: LD50 (Rat): 4,800 mg/kg LD50 (Mouse): 2,240 mg/kg Remarks: Evidence of phototoxicity was observed
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available
Acute toxicity (other routes of administration)	: LD50 (Rat): 4,840 mg/kg Application Route: Intramuscular LD50 (Mouse): 3,500 mg/kg Application Route: Subcutaneous

Ethanolamine:

Acute oral toxicity	: LD50 (Rat): 1,089 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate: 11 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Expert judgement Remarks: Based on national or regional regulation.
Acute dermal toxicity	: LD50 (Rabbit, female): 1,018 mg/kg

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:**

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

Remarks : No data available

Ethanolamine:

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

Sodium hydroxymethanesulphonate:

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 hydroxymethanesulphonate:

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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

Sodium hydroxymethanesulphinate:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**oxytetracycline:**

Genotoxicity in vitro	: Test Type: Microbial mutagenesis assay (Ames test) Result: negative Test Type: Mouse Lymphoma Metabolic activation: Metabolic activation Result: positive Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: equivocal Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral 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
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Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

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
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Sodium hydroxymethanesulphonate:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
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	: Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: positive
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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
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Germ cell mutagenicity - Assessment	: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.
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Carcinogenicity

Not classified based on available information.

Components:**oxytetracycline:**

Species	: Mouse
Application Route	: Oral
Exposure time	: 104 weeks
Result	: negative

Species	: Rat
Application Route	: Oral
Exposure time	: 103 weeks
Result	: equivocal
Target Organs	: Adrenal gland, Pituitary gland
Remarks	: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment	: Weight of evidence does not support classification as a carcinogen
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Reproductive toxicity

May damage the unborn child.

Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 2025/04/14	SDS Number: 5495950-00012	Date of last issue: 2025/02/07 Date of first issue: 2020/03/10
----------------	------------------------------	------------------------------	---

Components:**oxytetracycline:**

- | | |
|------------------------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported |
| Effects on foetal development | : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight
Result: No teratogenic effects
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:

- | | |
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| Effects on fertility | : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416 |
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Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 2025/04/14	SDS Number: 5495950-00012	Date of last issue: 2025/02/07 Date of first issue: 2020/03/10
----------------	------------------------------	------------------------------	---

	Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

Sodium hydroxymethanesulphonate:

Effects on fertility	: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive
Reproductive toxicity - Assessment	: Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

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

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

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

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.

Oxytetracycline (10%) Formulation

Version 4.0	Revision Date: 2025/04/14	SDS Number: 5495950-00012	Date of last issue: 2025/02/07 Date of first issue: 2020/03/10
----------------	------------------------------	------------------------------	---

Experience with human exposure**Components:****oxytetracycline:**

Ingestion	: Symptoms: Gastrointestinal disturbance, tooth discoloration Remarks: May cause birth defects.
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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 plants	: EC50 (Anabaena): 0.032 mg/l 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.
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Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): 65 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2.
Toxicity to algae/aquatic plants	:	ErC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 2.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (<i>Oryzias latipes</i> (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 (<i>Daphnia magna</i> (Water flea)): 0.85 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10 (<i>Pseudomonas putida</i>): > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

Sodium hydroxymethanesulphonate:

Toxicity to fish	:	LC50 (<i>Leuciscus idus</i> (Golden orfe)): > 10,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (<i>Desmodesmus subspicatus</i> (green algae)): 370 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (<i>Desmodesmus subspicatus</i> (green algae)): 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (<i>Danio rerio</i> (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 (<i>Daphnia magna</i> (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: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

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

Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.0	2025/04/14	5495950-00012	2025/02/07
			Date of first issue: 2020/03/10

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.

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.

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Oxytetracycline (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/07
4.0	2025/04/14	5495950-00012	Date of first issue: 2020/03/10

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Ethanolamine
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ID OEL	:	Indonesia. Occupational Exposure Limits

ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
ID OEL / NAB	:	Long term exposure limit
ID OEL / PSD	:	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 Sys-

Oxytetracycline (10%) Formulation

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tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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