

Oxytetracycline (10%) Liquid Formulation

Version 3.1 Revision Date: 2023/09/30 SDS Number: 10437525-00007 Date of last issue: 2023/04/04
Date of first issue: 2021/12/09

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline (10%) Liquid Formulation

Manufacturer or supplier's details

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

Hazard pictograms :   

Signal word : Danger

Hazard statements : H315 Causes skin irritation.

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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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
oxytetracycline	79-57-2	>= 2.5 -< 10
Ethanolamine	141-43-5	>= 1 -< 2.5
Sodium hydroxymethanesulphinate	6035-47-8	< 1

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

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

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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.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : light yellow
amber
translucent

Odour : No data available

Odour Threshold : No data available

pH : 8.0 - 9.0

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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 : No data available

Relative density : No data available

Density : 1.050 - 1.250 g/cm³

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

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Viscosity
 Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : Not applicable

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Product:

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

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l
 Exposure time: 4 h
 Test atmosphere: vapour
 Method: Calculation method

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

Components:**oxytetracycline:**

Acute oral toxicity : LD50 (Rat): 4,800 mg/kg
 LD50 (Mouse): 2,240 mg/kg

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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): > 5,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

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
Remarks : Based on data from similar materials

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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 hydroxymethanesulphinate:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**oxytetracycline:**

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

Ethanolamine:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Sodium hydroxymethanesulphinate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

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Components:

oxytetracycline:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Result: negative

Test Type: Mouse Lymphoma
Metabolic activation: Metabolic activation
Result: positive

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: equivocal

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: equivocal

Test Type: in vivo assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Ethanolamine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

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Method: OECD Test Guideline 471
 Result: negative
 Remarks: Based on data from similar materials

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
 Remarks: Based on data from similar materials

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

Carcinogenicity

Not classified based on available information.

Components:

oxytetracycline:

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

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

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

Reproductive toxicity

May damage the unborn child.

Components:

oxytetracycline:

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

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Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations

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

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

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight
Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Ethanolamine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Sodium hydroxymethanesulphinate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

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reproduction/developmental toxicity screening test
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 422
 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: positive
 Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Repeated dose toxicity

Components:

oxytetracycline:

Species : Rat
 LOAEL : 198 mg/kg
 Application Route : Oral
 Exposure time : 13 Weeks
 Target Organs : Bone
 Remarks : No significant adverse effects were reported

Species : Mouse
 LOAEL : 7,990 mg/kg
 Application Route : Oral
 Exposure time : 13 Weeks
 Target Organs : Bone

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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 hydroxymethanesulphinat:

Species : Rat
NOAEL : 600 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408
Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

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

Ingestion : Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

oxytetracycline:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 621 mg/l
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

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

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

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

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

M-Factor (Chronic aquatic : 10
toxicity)

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

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

Ethanolamine:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

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

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

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Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l
Exposure time: 41 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.85 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 13.5 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 4 h
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Ethanolamine:

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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
Remarks: Based on data from similar materials

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

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

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,
N.O.S.
(oxytetracycline)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

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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

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

Hazardous substances approved for use : Ethanolamine
Hydrochloric acid
Glycerine

Prohibited substances : Not applicable

Oxytetracycline (10%) Liquid Formulation

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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

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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/>

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

AllC - 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 Chemi-

Oxytetracycline (10%) Liquid Formulation

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cal 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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