

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Oxytetracycline (10%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.5	09/30/2023	10437532-00007	Date of first issue: 12/09/2021

### SECTION 1. IDENTIFICATION

Product name : Oxytetracycline (10%) Liquid Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
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@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin irritation : Category 2  
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 must not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection

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and face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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 attention.

P333 + P313 If skin irritation or rash occurs: Get medical attention.

P337 + P313 If eye irritation persists: Get medical attention.

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

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and 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)
Propylene glycol	57-55-6	$\geq 48.56 - \leq 57.8095$
Oxytetracycline	79-57-2	$\geq 8 - \leq 9.5238$
Glycerine	56-81-5	$\geq 6.56 - \leq 7.8095$
Ethanolamine	141-43-5	$\geq 1.12 - \leq 1.3333$
Sodium hydroxymethanesulphinate	6035-47-8	$\geq 0.4 - \leq 0.4762$

## 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.

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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 <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> )
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

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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.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA	10 mg/m <sup>3</sup>	US WEEL
Oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Ethanolamine	141-43-5	TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH

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		TWA	3 ppm 8 mg/m <sup>3</sup>	NIOSH REL
		ST	6 ppm 15 mg/m <sup>3</sup>	NIOSH REL
		TWA	3 ppm 6 mg/m <sup>3</sup>	OSHA Z-1

**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**  
**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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : liquid

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Color	:	light yellow
		amber
		translucent
Odor	:	No data available
Odor 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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.050 - 1.250 g/cm <sup>3</sup>
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	:	No data available
Explosive properties	:	Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation

Skin contact

Ingestion

Eye contact

#### 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: > 200 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:

##### Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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Assessment: The substance or mixture has no acute dermal toxicity

### 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

### Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

### Ethanolamine:

Acute oral toxicity : LD50 (Rat): 1,089 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor  
Method: Expert judgment  
Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 mg/kg

### Sodium hydroxymethanesulphinate:

Acute oral toxicity : LD50 (Rat): > 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:

#### Propylene glycol:

Species : Rabbit



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Method : OECD Test Guideline 404  
Result : No skin irritation

### **Oxytetracycline:**

Remarks : No data available

### **Glycerine:**

Species : Rabbit  
Result : No skin irritation

### **Ethanolamine:**

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

### **Sodium hydroxymethanesulphonate:**

Species : Rat  
Result : No skin irritation  
Remarks : Based on data from similar materials

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### **Components:**

#### **Propylene glycol:**

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

#### **Oxytetracycline:**

Remarks : No data available

#### **Glycerine:**

Species : Rabbit  
Result : No eye irritation

#### **Ethanolamine:**

Species : Rabbit  
Result : Irreversible effects on the eye

#### **Sodium hydroxymethanesulphonate:**

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

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### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Propylene glycol:

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

##### 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 hydroxymethanesulphinate:

Test Type	: Maximization Test
Routes of exposure	: 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.

#### Components:

##### Propylene glycol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
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Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
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### 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.

### Glycerine:

- Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

### 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

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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  
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:

#### Propylene glycol:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

#### 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.

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

### Glycerine:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child.

### Components:

#### Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

#### Oxytetracycline:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 18 mg/kg body weight  
Result: No effects on fertility., No effect on reproduction capacity., No significant adverse effects were reported

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

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight

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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.

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.

### Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### 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

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### 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  
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: 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:

##### Propylene glycol:

Species : Rat, male  
NOAEL :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

##### Oxytetracycline:

Species : Rat  
LOAEL : 198 mg/kg  
Application Route : Oral

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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

### Glycerine:

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 0.622 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 8,000 - 10,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

Species : Rabbit  
NOAEL : 5,040 mg/kg  
Application Route : Skin contact  
Exposure time : 45 Weeks

### 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



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## Oxytetracycline (10%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.5	09/30/2023	10437532-00007	Date of first issue: 12/09/2021

Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

### Sodium hydroxymethanesulphonate:

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.

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Propylene glycol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

#### **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

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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 plants : EC50 (Anabaena): 0.032 mg/l  
Exposure time: 72 h

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

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

### Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l  
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

### Ethanolamine:

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

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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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 hydroxymethanesulphonate:

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:

#### Propylene glycol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

#### Glycerine:

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Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

### Ethanolamine:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 90 %  
Exposure time: 21 d  
Method: OECD Test Guideline 301A

### Sodium hydroxymethanesulphonate:

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:

#### Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

#### Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1.75

#### 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

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number	: UN 3082
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class	: 9
Packing group	: III
Labels	: 9
Environmentally hazardous	: yes

##### 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

##### 49 CFR

UN/ID/NA number	: UN 3082
Proper shipping name	: Environmentally hazardous substance, liquid, n.o.s. (Oxytetracycline)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Oxytetracycline)
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it

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may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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

### CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization  
Reproductive toxicity  
Skin corrosion or irritation  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Propylene glycol	57-55-6
Water	7732-18-5
Oxytetracycline	79-57-2
Glycerine	56-81-5
Polyvinyl pyrrolidone	9003-39-8
Ethanolamine	141-43-5
Hydrochloric acid	7647-01-0

#### California Prop. 65

WARNING: This product can expose you to chemicals including Oxytetracycline, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

Polyvinyl pyrrolidone	9003-39-8
Ethanolamine	141-43-5

#### California Permissible Exposure Limits for Chemical Contaminants

Glycerine	56-81-5
Ethanolamine	141-43-5

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

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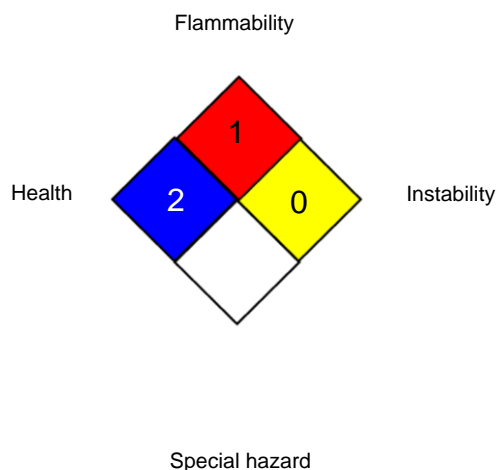
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AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;

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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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Revision Date : 09/30/2023

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.

US / Z8