SAFETY DATA SHEET
according to the Hazardous Products Regulations

Oxytetracycline (10%) Liquid Formulation

SECTION 1. IDENTIFICATION

Product name : Oxytetracycline (10%) Liquid Formulation
Other means of identification : No data available

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 Hazardous Products Regulations
Skin irritation : Category 2
Eye irritation : Category 2A
Skin sensitization : Sub-category 1A
Reproductive toxicity : Category 1A

GHS label elements
Hazard pictograms : 

Signal Word : Danger
Hazard Statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360D May damage the unborn child.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Oxytetracycline</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
</tr>
<tr>
<td></td>
<td>Ethanolamine</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxymethanesulfinate</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with plenty of water.
for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May damage the unborn child.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
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 (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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid breathing mist or vapors.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 23
Oxytetracycline (10%) Liquid Formulation

Propylene glycol 57-55-6 | TWA (Vapour and aerosols) | 50 ppm 155 mg/m³ | CA ON OEL

| | TWA (aerosol) | 10 mg/m³ | CA ON OEL

Oxytetracycline 79-57-2 | TWA | 500 µg/m³ (OEL 2) | Internal

Further information: DSEN

<table>
<thead>
<tr>
<th>Material</th>
<th>Wipe limit</th>
<th>TWA (Mist)</th>
<th>TWA (Respirable mist)</th>
<th>TWAEV (Mist)</th>
<th>STEL</th>
<th>TWA</th>
<th>STEL</th>
<th>TWAEV</th>
<th>STEV</th>
<th>TWA</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>100 µg/100 cm²</td>
<td>10 mg/m³</td>
<td>3 mg/m³</td>
<td>10 mg/m³</td>
<td>6 ppm</td>
<td>3 ppm</td>
<td>6 ppm</td>
<td>3 ppm</td>
<td>6 ppm</td>
<td>3 ppm</td>
<td>6 ppm</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
<td>7.5 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>10 mg/m³</td>
<td>3 mg/m³</td>
<td>3 mg/m³</td>
<td>15 mg/m³</td>
<td>7.5 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapor type

Hand protection: Chemical-resistant gloves

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...
Oxytetracycline (10%) Liquid Formulation

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>light yellow; amber; translucent</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>8.0 - 9.0</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.050 - 1.250 g/cm³</td>
</tr>
</tbody>
</table>
Oxytetracycline (10%) Liquid Formulation

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: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: Calculation method
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Oxytetracycline (10%) Liquid Formulation

Acute dermal toxicity

Acute toxicity estimate: > 2,000 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
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
### Acute dermal toxicity
LD50 (Rat): > 2,000 mg/kg

### Skin corrosion/irritation
Causes skin irritation.

#### Components:

**Propylene glycol:**
- **Species**: Rabbit
- **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 hydroxymethanesulphinate:**
- **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 hydroxymethanesulphinate:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

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
Oxytetracycline (10%) Liquid Formulation

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
- Test Type: Chromosome aberration test in vitro
  Result: negative

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

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  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 (10%) Liquid Formulation

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

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

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
Oxytetracycline (10%) Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>09/30/2023</td>
<td>10437521-00007</td>
<td>04/04/2023</td>
<td>12/09/2021</td>
</tr>
</tbody>
</table>

Embryo-fetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss, Skeletal malformations.

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

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

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

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
Oxytetracycline (10%) Liquid Formulation

Effects on fetal development:
- Test Type: Embryo-fetal 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 reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative

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

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: >= 1,700 mg/kg
Application Route: Ingestion
**Oxytetracycline (10%) Liquid Formulation**

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>2 y</th>
</tr>
</thead>
</table>

**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
- **TargetOrgans:** 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
Oxytetracycline (10%) Liquid Formulation

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: 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 (10%) Liquid Formulation

**SAFETY DATA SHEET**

according to the Hazardous Products Regulations

**Oxytetracycline (10%) Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>09/30/2023</td>
<td>10437521-00007</td>
<td>04/04/2023</td>
<td>12/09/2021</td>
</tr>
</tbody>
</table>

### 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 (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  

#### Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 65 mg/l  
  Exposure time: 48 h  

#### Toxicity to algae/aquatic plants:
- ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Oxytetracycline (10%) Liquid Formulation

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:

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

Glycerine:
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 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:

Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Oxytetracycline)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant: yes (Oxytetracycline)

**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

The ingredients of this product are reported in the following inventories:
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH/TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH/STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>CA AB OEL</td>
<td>Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)</td>
</tr>
<tr>
<td>CA BC OEL</td>
<td>Canada. British Columbia OEL</td>
</tr>
<tr>
<td>CA ON OEL</td>
<td>Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.</td>
</tr>
<tr>
<td>CA QC OEL</td>
<td>Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants</td>
</tr>
<tr>
<td>AC/GIH/ELx</td>
<td>Loading rate associated with x% response</td>
</tr>
<tr>
<td>ENCS</td>
<td>Existing and New Chemical Substances (Japan)</td>
</tr>
<tr>
<td>ECx</td>
<td>Concentration associated with x% response</td>
</tr>
<tr>
<td>ErCX</td>
<td>Concentration associated with x% growth rate response</td>
</tr>
<tr>
<td>EM</td>
<td>Emergency Schedule</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>IBC</td>
<td>International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk</td>
</tr>
<tr>
<td>IBCA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IBC50</td>
<td>Concentration associated with 50% response</td>
</tr>
<tr>
<td>IBC/STEL</td>
<td>short-term exposure limit</td>
</tr>
<tr>
<td>IBC/TWA</td>
<td>Time-Weighted Average Limit (TWA)</td>
</tr>
<tr>
<td>IBC/STEV</td>
<td>Short-term exposure value</td>
</tr>
<tr>
<td>IECSC</td>
<td>Inventory of Existing Chemical Substances in China</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods</td>
</tr>
<tr>
<td>ITC</td>
<td>International Civil Aviation Organization</td>
</tr>
</tbody>
</table>

**Additional abbreviations:**
- **AB**: Alberta, Canada
- **AC**: American Cancer Society
- **ADAMS**: American Disposal and Management Society
- **AIHC**: Australian Inventory of Hazardous Chemicals
- **AIC**: American Industrial Chemistry
- **AICS**: Australian Inventory of Chemical Substances
- **AIIC**: Australian Inventory of Industrial Chemicals
- **ANSS**: American National Standards Society
- **ANST**: Australian National Standards
- **AOP**: American Oil and Petroleum Industry
- **ASTM**: American Society for Testing and Materials
- **AIIA**: Australian Industrial and Agricultural Association
- **C1**: Carbon tetrachloride
- **C2**: Chloroform
- **C3**: Carbon disulfide
- **C4**: Carbon tetrachloride
- **C5**: Chloroform
- **C6**: Carbon disulfide
- **C7**: Carbon tetrachloride
- **C8**: Chloroform
- **C9**: Carbon disulfide
- **C10**: Carbon tetrachloride
- **C11**: Chloroform
- **C12**: Carbon disulfide
- **C13**: Carbon tetrachloride
- **C14**: Chloroform
- **C15**: Carbon disulfide
- **C16**: Carbon tetrachloride
- **C17**: Chloroform
- **C18**: Carbon disulfide
- **C19**: Carbon tetrachloride
- **C20**: Chloroform
- **C21**: Carbon disulfide
- **C22**: Carbon tetrachloride
- **C23**: Chloroform
- **C24**: Carbon disulfide
- **C25**: Carbon tetrachloride
- **C26**: Chloroform
- **C27**: Carbon disulfide
- **C28**: Carbon tetrachloride
- **C29**: Chloroform
- **C30**: Carbon disulfide
- **C31**: Carbon tetrachloride
- **C32**: Chloroform
- **C33**: Carbon disulfide
- **C34**: Carbon tetrachloride
- **C35**: Chloroform
- **C36**: Carbon disulfide
- **C37**: Carbon tetrachloride
- **C38**: Chloroform
- **C39**: Carbon disulfide
- **C40**: Carbon tetrachloride
- **C41**: Chloroform
- **C42**: Carbon disulfide
- **C43**: Carbon tetrachloride
- **C44**: Chloroform
- **C45**: Carbon disulfide
- **C46**: Carbon tetrachloride
- **C47**: Chloroform
- **C48**: Carbon disulfide
- **C49**: Carbon tetrachloride
- **C50**: Chloroform
- **C51**: Carbon disulfide
- **C52**: Carbon tetrachloride
- **C53**: Chloroform
- **C54**: Carbon disulfide
- **C55**: Carbon tetrachloride
- **C56**: Chloroform
- **C57**: Carbon disulfide
- **C58**: Carbon tetrachloride
- **C59**: Chloroform
- **C60**: Carbon disulfide
- **C61**: Carbon tetrachloride
- **C62**: Chloroform
- **C63**: Carbon disulfide
- **C64**: Carbon tetrachloride
- **C65**: Chloroform
- **C66**: Carbon disulfide
- **C67**: Carbon tetrachloride
- **C68**: Chloroform
- **C69**: Carbon disulfide
- **C70**: Carbon tetrachloride
- **C71**: Chloroform
- **C72**: Carbon disulfide
- **C73**: Carbon tetrachloride
- **C74**: Chloroform
- **C75**: Carbon disulfide
- **C76**: Carbon tetrachloride
- **C77**: Chloroform
- **C78**: Carbon disulfide
- **C79**: Carbon tetrachloride
- **C80**: Chloroform
- **C81**: Carbon disulfide
- **C82**: Carbon tetrachloride
- **C83**: Chloroform
- **C84**: Carbon disulfide
- **C85**: Carbon tetrachloride
- **C86**: Chloroform
- **C87**: Carbon disulfide
- **C88**: Carbon tetrachloride
- **C89**: Chloroform
- **C90**: Carbon disulfide
- **C91**: Carbon tetrachloride
- **C92**: Chloroform
- **C93**: Carbon disulfide
- **C94**: Carbon tetrachloride
- **C95**: Chloroform
- **C96**: Carbon disulfide
- **C97**: Carbon tetrachloride
- **C98**: Chloroform
- **C99**: Carbon disulfide
- **C100**: Carbon tetrachloride
- **C101**: Chloroform
- **C102**: Carbon disulfide
- **C103**: Carbon tetrachloride
- **C104**: Chloroform
- **C105**: Carbon disulfide
- **C106**: Carbon tetrachloride
- **C107**: Chloroform
# SAFETY DATA SHEET
according to the Hazardous Products Regulations

## Oxytetracycline (10%) Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>09/30/2023</td>
<td>10437521-00007</td>
<td>04/04/2023</td>
<td>12/09/2021</td>
</tr>
</tbody>
</table>

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


Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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.

CA / Z8