SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Oxytetracycline (10%) Formulation

Version 1.2  Revision Date: 2021/08/27  SDS Number: 5495948-00003  Date of last issue: 2020/10/10

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Oxytetracycline (10%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: suspension
Colour: No data available
Odour: No data available

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May damage the unborn child. Very toxic to aquatic life with long lasting effects.

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:
Oxytetracycline (10%) Formulation

Signal word : Danger

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

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

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction. May damage the unborn child.

Environmental hazards
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td></td>
</tr>
</tbody>
</table>

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 (CO2)

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

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

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

7. HANDLING AND STORAGE

Handling

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.

Storage

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>PC-TWA</td>
<td>8 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-STEL</td>
<td>15 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>3 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>6 ppm</td>
<td>ACGIH</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 vapour type

Eye/face protection:
- Wear safety glasses with side shields or 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.

Hand protection:
- Material: Chemical-resistant gloves

Hygiene measures:
- If exposure to chemical is likely during typical use, provide
eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</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>Not applicable</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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**Partition coefficient: n-octanol/water**
Not applicable

**Auto-ignition temperature**
No data available

**Decomposition temperature**
No data available

**Viscosity**
- **Viscosity, kinematic**
  Not applicable

**Explosive properties**
Not explosive

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

**Molecular weight**
No data available

**Particle size**
Not applicable

### 10. STABILITY AND REACTIVITY

**Reactivity**
Not classified as a reactivity hazard.

**Chemical stability**
Stable under normal conditions.

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

**Conditions to avoid**
None known.

**Incompatible materials**
Oxidizing agents

**Hazardous decomposition products**
No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

**Exposure routes**
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Acute toxicity estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 40 mg/l</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>&gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**
oxytetracycline:
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Acute oral toxicity : LD50 (Rat): 4,800 mg/kg
LD50 (Mouse): 2,240 mg/kg
Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) :
LD50 (Rat): 4,840 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 3,500 mg/kg
Application Route: Subcutaneous

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

Acute inhalation toxicity :
Acute toxicity estimate: 11 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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
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Remarks  :  Based on data from similar materials

**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.
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)
  Method: OECD Test Guideline 471
  Result: negative
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<thead>
<tr>
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</tr>
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<tr>
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<td>2020/03/10</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>104 weeks</td>
<td>negative</td>
<td>Adrenal gland, Pituitary gland</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>103 weeks</td>
<td>equivocal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

## Reproductive toxicity
May damage the unborn child.

## Components:

### Oxytetracycline:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Application Route</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Oral</td>
<td>Fertility: NOAEL: 18 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: No effects on fertility, No effect on reproduc-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>tion capacity, No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Application Route</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Oral</td>
<td>Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: Postimplantation loss., Skeletal malformations</td>
</tr>
</tbody>
</table>
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 reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative
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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
- Remarks: No significant adverse effects were reported

- Species: Dog
- NOAEL: 125 mg/kg
- LOAEL: 250 mg/kg
- Application Route: Oral
- Exposure time: 12 Months
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Target Organs: Testis
Remarks: Significant toxicity observed in testing

Species: Rat
NOAEL: 40 mg/kg
LOAEL: 100 mg/kg
Application Route: Intraperitoneal
Exposure time: 14 Days
Target Organs: Kidney

Ethanolamine:
Species: Rat
NOAEL: > 120 mg/kg
Application Route: Ingestion
Exposure time: > 75 Days
Remarks: Based on data from similar materials

Species: Rat
NOAEL: >= 0.15 mg/l
Application Route: Inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Sodium hydroxymethanesulphinate:
Species: Rat
NOAEL: 600 mg/kg
Application Route: Ingestion
Exposure time: 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.

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
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<tr>
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</tr>
</tbody>
</table>

**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

**M-Factor (Acute aquatic toxicity)**: 10

**M-Factor (Chronic aquatic toxicity)**: 10

**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

**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
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**: NOEC (Daphnia magna (Water flea)): 0.85 mg/l
aquatic invertebrates (Chronic toxicity)
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:
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: 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

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
### Oxytetracycline (10%) Formulation

**Version**: 1.2  |  **Revision Date**: 2021/08/27  |  **SDS Number**: 5495948-00003  |  **Date of last issue**: 2020/10/10  |  **Date of first issue**: 2020/03/10

- **Packing group**: III
- **Labels**: 9
- **EmS Code**: F-A, S-F
- **Marine pollutant**: yes

**National Regulations**

**GB 6944/12268**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 15. REGULATORY INFORMATION

**National regulatory information**

**Law on the Prevention and Control of Occupational Diseases**

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 16. OTHER INFORMATION

**Further information**

Sources of key data used to compile the Safety Data Sheet:


**Date format**: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CN OEL**: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

- **ACGIH / TWA**: 8-hour, time-weighted average
Oxytetracycline (10%) Formulation

Version 1.2 Revision Date: 2021/08/27 SDS Number: 5495948-00003 Date of last issue: 2020/10/10 Date of first issue: 2020/03/10

ACGIH / STEL : Short-term exposure limit
CN OEL / PC-TWA : Permissible concentration - time weighted average
CN OEL / PC-STEL : Permissible concentration - short term exposure limit

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

Disclaimer
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.

CN / EN