SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline (10%) Formulation

Manufacturer or supplier's details
Company : MSD
Address : JL Raya Pandaan KM. 48
          Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2A
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : ![Image]
Signal word : Danger
Hazard statements : H315 Causes skin irritation.
                    H317 May cause an allergic skin reaction.
                    H319 Causes serious eye irritation.
                    H360D May damage the unborn child.
                    H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

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

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

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>oxytetracycline</td>
</tr>
<tr>
<td></td>
<td>Ethanolamine</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxymethanesulphinate</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)
- Dry chemical

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

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

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

Advice on safe handling:
Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

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>
</tbody>
</table>

Further information: DSEN
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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available
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.
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: vapour
  Method: Calculation method
- **Acute dermal toxicity**: Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

**Components:**

- **oxytetracycline:**
  - **Acute oral toxicity**: LD50 (Rat): 4,800 mg/kg
    LD50 (Mouse): 2,240 mg/kg
    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
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Version: 1.2  
Revision Date: 2021/08/27  
SDS Number: 5495950-00003  
Date of last issue: 2020/10/10  
Date of first issue: 2020/03/10

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

Sodium hydroxymethanesulphinate:
Acute oral toxicity:  
LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

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

Skin corrosion/irritation:
Causes skin irritation.

Components:
oxytetracycline:
Remarks: No data available

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

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

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
- 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
  Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Method: OECD Test Guideline 474
  Result: positive
  Remarks: Based on data from similar materials

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

Carcinogenicity:
Not classified based on available information.

Components:

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

- Species: Rat
- Application Route: Oral
- Exposure time: 103 weeks
**Result**

equivocal

**Target Organs**

Adrenal gland, Pituitary gland

**Remarks**

The mechanism or mode of action may not be relevant in humans.

**Carcinogenicity - Assessment**

Weight of evidence does not support classification as a carcinogen

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**Oxytetracycline:**

**Effects on fertility**

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

**Effects on foetal development**

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

Test Type: Embryo-foetal development  
Species: Mouse  
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: 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
- **Remarks:** Based on data from similar materials

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

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

**STOT - single exposure**
Not classified based on available information.

**Components:**

**Ethanolamine:**
- **Assessment:** May cause respiratory irritation.

**STOT - repeated exposure**
Not classified based on available information.

**Components:**

**Ethanolamine:**
- **Assessment:** No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.
## Repeated dose toxicity

### Components:

**oxytetracycline:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>198 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>7,990 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>125 mg/kg</td>
<td>250 mg/kg</td>
<td>Oral</td>
<td>12 Months</td>
<td>Testis</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>40 mg/kg</td>
<td>Intrapерitoneal</td>
<td>14 Days</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

**Ethanolamine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 120 mg/kg</td>
<td>Ingestion</td>
<td>&gt; 75 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 0.15 mg/l</td>
<td>Inhilation (dust/mist/fume)</td>
<td>28 Days</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

**Sodium hydroxymethanesulphinate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>600 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>OECD Test Guideline 408</td>
</tr>
</tbody>
</table>

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

- **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
### Oxytetracycline (10%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
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<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>2021/08/27</td>
<td>5495950-00003</td>
<td>2020/10/10</td>
<td>2020/03/10</td>
</tr>
</tbody>
</table>

**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 aquatic invertebrates (Chronic toxicity):**  
NOEC (Daphnia magna (Water flea)): 0.85 mg/l  
Exposure time: 21 d

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

---

**Sodium hydroxymethanesulphinate:**

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

**Toxicity to daphnia and other aquatic invertebrates:**  
EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
**Method:** OECD Test Guideline 202

Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants:**  
ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l  
Exposure time: 72 h  
**Method:** OECD Test Guideline 201

Remarks: Based on data from similar materials

**Toxicity to fish (Chronic toxicity):**  
NOEC (Danio rerio (zebra fish)): 13.5 mg/l  
Exposure time: 35 d  
**Method:** OECD Test Guideline 210

Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**  
NOEC (Daphnia magna (Water flea)): 5.6 mg/l  
Exposure time: 21 d  
**Method:** OECD Test Guideline 211

Remarks: Based on data from similar materials

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

Persistence and degradability

Components:
Ethanolamine:
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:

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
SAFETY DATA SHEET

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<thead>
<tr>
<th>Labels</th>
<th>9</th>
</tr>
</thead>
</table>

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

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

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

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

**15. REGULATORY INFORMATION**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

- Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
  - Hazardous substances that must be registered: Not applicable

- Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
  - Hazardous substances approved for use: Ethanolamine
  - Prohibited substances: Not applicable
  - Restricted substances: Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized 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 Substanc-
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Version 1.2  Revision Date: 2021/08/27  SDS Number: 5495950-00003  Date of last issue: 2020/10/10

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

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