SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline (10%) Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin irritation : Category 2
Eye irritation : Category 2A
Skin sensitization : Category 1
Reproductive toxicity : Category 1A

GHS label elements

Hazard pictograms : 

Signal Word : Danger

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

Precautionary Statements :  

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

Storage:
P405 Store locked up.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>&gt;= 1 -&lt; 3</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&gt;= 0.1 -&lt; 1</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.

Most important symptoms : Causes skin irritation.
and effects, both acute and delayed
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 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 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.

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.

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
  - 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>
<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

Wipe limit 100 µg/100 cm² | Internal
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Ethanolamine | 141-43-5 | VLE-PPT | 3 ppm | NOM-010-STPS-2014
VLE-CT | 6 ppm | NOM-010-STPS-2014
TWA | 3 ppm | ACGIH
STEL | 6 ppm | ACGIH

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 Material: Chemical-resistant gloves
Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection: Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance: suspension
Color: No data available
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: Not applicable
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: 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

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 40 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
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: vapor
Method: Expert judgment
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
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: Rat
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:
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:

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
  - 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 fetal development:
Species: Rat
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 48 mg/kg body weight

Species: Mouse
Application Route: Oral
Embryo-fetal toxicity.: NOAEL: 1,500 mg/kg body weight
Result: No teratogenic effects.
Remarks: Maternal toxicity observed.

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

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.

Ethanolamine:

Effects on fertility:
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

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

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 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:

Oxytetracycline:
Species: Rat
LOAEL: 198 mg/kg
### Oxytetracycline (10%) Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<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>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>Rat</td>
<td>40 mg/kg</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Testis</td>
<td>Significant toxicity observed in testing</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>Inhalation (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>
<th>Remarks</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>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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:

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

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: ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8
### Oxytetracycline (10%) Formulation

<table>
<thead>
<tr>
<th>Plants</th>
<th>mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

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

Mobility in soil  
No data available

Other adverse effects  
No data available

SECTION 13. DISPOSAL CONSIDERATIONS  
Disposal methods  
Waste from residues: Dispose of in accordance with local regulations.  
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

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
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Version 1.2  Revision Date: 27.08.2021  SDS Number: 5495953-00003  Date of last issue: 10.10.2020  Date of first issue: 10.03.2020

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**

**NOM-002-SCT**

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.

**SECTION 15. REGULATORY INFORMATION**

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value
NOM-010-STPS-2014 / VLE-CT : Short term exposure limit value

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; ICSO - 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


Revision Date: 27.08.2021
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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