Oxytetracycline (10%) Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Oxytetracycline (10%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilshealan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2 : H315: Causes skin irritation.
Eye irritation, Category 2 : H319: Causes serious eye irritation.
Skin sensitisation, Category 1 : H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A : H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline (10%) Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 5499550-00004  Date of last issue: 09.04.2021  Date of first issue: 10.03.2020

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
- Prevention:
  - P201 Obtain special instructions before use.
  - P264 Wash skin thoroughly after handling.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
- Response:
  - P308 + P313 IF exposed or concerned: Get medical advice/attention.
  - P391 Collect spillage.

Hazardous components which must be listed on the label:
- oxytetracycline

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>201-212-8</td>
<td></td>
<td></td>
<td>Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline (10%) Formulation

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Date of last issue: 09.04.2021
Date of first issue: 10.03.2020

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

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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

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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.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
</tr>
<tr>
<td>oxytetracycline</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Ethanolamine</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
skin when they come in contact with it, and be absorbed into the body

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanolamine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>3.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.24 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>3.75 mg/kg bw/day</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanolamine</td>
<td>Fresh water</td>
<td>0.085 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.028 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0085 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.434 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.0434 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0367 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

**8.2 Exposure controls**

**Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Laboratory operations do not require special containment.

**Personal protective equipment**

**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.

**Hand protection**

Material: Chemical-resistant gloves

**Skin and body protection**

Work uniform or laboratory coat.

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387
SAFETY DATA SHEET
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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</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>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>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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</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>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

9.2 Other information

Explosives : Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: Not applicable
Molecular weight: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 toxicity estimate: 1,089 mg/kg
  - Method: Calculation method
- **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
  - Acute toxicity estimate: 1,018 mg/kg
  - Method: Calculation method

**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
Method : OECD Test Guideline 405
Result : No eye irritation
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:
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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
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
### Effects on foetal development

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>NOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>48 mg/kg body weight</td>
<td>18 mg/kg body weight</td>
<td>No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2,100 mg/kg body weight</td>
<td>1,500 mg/kg body weight</td>
<td>No teratogenic effects</td>
<td>Maternal toxicity observed.</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>41.5 mg/kg body weight</td>
<td>20.75 mg/kg body weight</td>
<td>Postimplantation loss., No foetal abnormalities</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>Intramuscular</td>
<td>20.75 mg/kg body weight</td>
<td>1,200 mg/kg body weight</td>
<td>Skeletal and visceral variations, Postimplantation loss.</td>
<td></td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment

Positive evidence of adverse effects on development from human epidemiological studies.

---

**Ethanolamine:**

### Effects on fertility

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>LOAEL</th>
<th>NOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>OECD Test Guideline 416</td>
<td>negative</td>
<td>Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Effects on foetal development

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>No effects on fertility</td>
<td>No effect on reproduction capacity</td>
<td></td>
</tr>
</tbody>
</table>
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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:
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
Oxytetracycline (10%) Formulation

LOAEL: 7,990 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

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

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

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to
Experience with human exposure

Components:

oxytetracycline:
Ingestion:
Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

SECTION 12: Ecological information

12.1 Toxicity

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

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

M-Factor (Chronic aquatic toxicity):
10
### 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 microorganisms**
- EC10 (Pseudomonas putida): > 1,000 mg/l
  - Exposure time: 30 min
  - Method: OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**
- NOEC: 1.24 mg/l
  - Exposure time: 41 d
  - Species: Oryzias latipes (Orange-red killifish)
  - Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC: 0.85 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)

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

**Toxicity to fish (Chronic toxicity)**
- NOEC: 13.5 mg/l
  - Exposure time: 35 d
  - Species: Danio rerio (zebra fish)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC: 5.6 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211
- Remarks: Based on data from similar materials

**12.2 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

**12.3 Bioaccumulative potential**

**Components:**

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

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

**Product:**

- Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**

**Product:**

- Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

<table>
<thead>
<tr>
<th>Product</th>
<th>Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminated packaging</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

SECTION 14: Transport information

14.1 UN number or ID number

<table>
<thead>
<tr>
<th>UN/ADR/RID/IMDG/IATA</th>
<th>3082</th>
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</thead>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>UN/ADR/RID/IMDG/IATA</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)</th>
</tr>
</thead>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>UN/ADR/RID/IMDG/IATA</th>
<th>9</th>
</tr>
</thead>
</table>
Oxytetracycline (10%) Formulation

14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes
IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

E1 ENVIRONMENTAL HAZARDS
Quantity 1 Quantity 2
100 t 200 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline (10%) Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 5499550-00004
Date of last issue: 09.04.2021
Date of first issue: 10.03.2020

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
H341: Suspected of causing genetic defects.
H360D: May damage the unborn child.
H361d: Suspected of damaging the unborn child.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Dam.: Serious eye damage
Muta.: Germ cell mutagenicity
Repr.: Reproductive toxicity
Skin Corr.: Skin corrosion
Skin Sens.: Skin sensitisation
STOT SE: Specific target organ toxicity - single exposure
2006/15/EC: Europe. Indicative occupational exposure limit values
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values
2006/15/EC / TWA: Limit Value - eight hours
2006/15/EC / STEL: Short term exposure limit
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); EmCx - Concentration associated with x% growth rate response; 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 Organiza-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline (10%) Formulation

Version 1.3 Revision Date: 27.08.2021 SDS Number: 5499550-00004 Date of last issue: 09.04.2021

Classification of the mixture: Classification procedure:
Skin Irrit. 2 H315 Calculation method
Eye Irrit. 2 H319 Calculation method
Skin Sens. 1 H317 Calculation method
Repr. 1A H360D Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

Further information:

IE / EN