1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
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: 
Signal word: Danger
Hazard statements:  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H360FD May damage fertility. 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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-

Version 3.1 Revision Date: 23.03.2020 SDS Number: 1313896-00010 Date of last issue: 11.12.2019 Date of first issue: 20.02.2017

| Magnesium oxide | 1309-48-4 | >= 1 - < 5 |
| Sodium [2-[2,6-dichlorophenyl]amino]phenyl]acetate | 15307-79-6 | >= 0.25 - < 1 |
| Sodium hydroxymethanesulphinate | 149-44-0 | >= 0.1 - < 1 |

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 soap and plenty of water. Remove 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: May cause an allergic skin reaction. Causes serious eye irritation. May damage fertility. 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


Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.


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.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions**:
- Discharge into the environment must be avoided.
- 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 dyeing or other appropriate containment to keep material from spreading. If dyed 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.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- 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/PERSOAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
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</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
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<tr>
<td>pH</td>
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<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>47.62 mm²/s</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:
2-Pyrrolidone:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
## Oxytetracycline / Diclofenac Liquid Formulation

**Version**: 3.1  \hspace{1cm} **Revision Date**: 23.03.2020  \hspace{1cm} **SDS Number**: 1313896-00010  \hspace{1cm} **Date of last issue**: 11.12.2019  \hspace{1cm} **Date of first issue**: 20.02.2017

### 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

### Benzyl alcohol:

- **Acute oral toxicity**: LD50 (Rat): 1,620 mg/kg

- **Acute inhalation toxicity**: LC50 (Rat): > 4.178 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist  
  Method: OECD Test Guideline 403

### Magnesium oxide:

- **Acute oral toxicity**:  
  LD50 (Rat): > 2,000 mg/kg  
  Method: OECD Test Guideline 423  
  Assessment: The substance or mixture has no acute oral toxicity  
  Remarks: Based on data from similar materials

- **Acute inhalation toxicity**:  
  LC50 (Rat): > 2.1 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist  
  Method: OECD Test Guideline 403  
  Remarks: Based on data from similar materials

### Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

- **Acute oral toxicity**:  
  LD50 (Rat): 55 - 240 mg/kg  
  LD50 (Mouse): 170 - 389 mg/kg

- **Acute toxicity (other routes of administration)**:  
  LD50 (Rat): 97 - 161 mg/kg  
  Application Route: Intravenous  
  LD50 (Mouse): 92 - 147 mg/kg  
  Application Route: Intravenous

### Sodium hydroxymethanesulphinate:

- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

**Components:**

**2-Pyrrolidone:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Oxytetracycline:**
Remarks: No data available

**Benzyl alcohol:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Magnesium oxide:**
Method: OECD Test Guideline 431
Result: No skin irritation
Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Result: irritating

**Sodium hydroxymethanesulphinate:**
Species: Rat
Result: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**2-Pyrrolidone:**
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days

**Oxytetracycline:**
Remarks: No data available

**Benzyl alcohol:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

**Magnesium oxide:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Result: Mild eye irritation

**Sodium hydroxymethanesulphinate:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**2-Pyrrolidone:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

**Oxytetracycline:**
Test Type: Human repeat insult patch test (HRIPT)
Result: Sensitiser

**Benzyl alcohol:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Magnesium oxide:
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

Sodium hydroxymethanesulphinate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
2-Pyrrolidone:
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
Remarks: Based on data from similar materials
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

Oxytetracycline:
Genotoxicity in vitro:
Test Type: Microbial mutagenesis assay (Ames test)
Result: negative
Test Type: Mouse Lymphoma
Metabolic activation: Metabolic activation
Result: positive
Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: equivocal

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Oral
  Result: equivocal

- Test Type: in vivo assay
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Benzyl alcohol:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

**Magnesium oxide:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

  Test Type: Mouse Lymphoma
  Result: negative
Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: CHO  
Result: negative

Sodium hydroxymethanesulphinate:  
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: positive

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

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

Carcinogenicity  
Not classified based on available information.

Components:  

2-Pyrrolidone:  
Species : Mouse  
Application Route : Ingestion  
Exposure time : 18 month(s)  
Result : negative  
Remarks : Based on data from similar materials

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

**Benzyl alcohol:**
Species: Mouse  
Application Route: Ingestion  
Exposure time: 103 weeks  
Method: OECD Test Guideline 451  
Result: negative

**Magnesium oxide:**
Species: Mouse  
Application Route: Ingestion  
Exposure time: 96 weeks  
Result: negative  
Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Species: Rat  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative  
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

**Reproductive toxicity**
May damage fertility. May damage the unborn child.

**Components:**

**2-Pyrrolidone:**
Effects on fertility: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: positive  
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive

**Reproductive toxicity - Assessment:** Clear evidence of adverse effects on sexual function and fertility, based on animal experiments. Clear evidence of adverse effects on development, based on animal experiments.

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

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

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

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

Benzy alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Application Route: Ingestion
Result: negative

Magnesium oxide:
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: 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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Effects on fertility: Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 5 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

Sodium hydroxymethanesulphinate:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-

Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

**Sodium [2-(2,6-dichlorophenyl)amino]phenylacetate:**
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

**2-Pyrrolidone:**
Species: Rat
NOAEL: 207 mg/kg
Application Route: Ingestion
Exposure time: 3 Months
Method: OECD Test Guideline 408

**Oxytetracycline:**
Species: Rat
LOAEL: 198 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

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

Species: Dog
NOAEL: 125 mg/kg
LOAEL: 250 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Testis
Remarks: Significant toxicity observed in testing
<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>40 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**
- **Species:** Rat
- **NOAEL:** 1.072 mg/l
- **Application Route:** Inhalation (dust/mist/fume)
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 412

**Magnesium oxide:**
- **Species:** Rat
- **NOAEL:** >= 1,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 407
- **Remarks:** Based on data from similar materials

**Sodium [2-(2,6-dichlorophenyl)amino]phenyl]acetate:**
- **Species:** Rat
- **LOAEL:** 0.25 mg/kg
- **Application Route:** Oral
- **Exposure time:** 98 w
- **Target Organs:** Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

**Species**
- **Dog**
- **LOAEL:** 1 mg/kg
- **Application Route:** Oral
- **Exposure time:** 12 w
- **Target Organs:** Blood

**Species**
- **Baboon**
- **NOAEL:** 0.5 mg/kg
- **LOAEL:** 5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 52 w
- **Target Organs:** Gastrointestinal tract, Blood

**Symptoms:** constipation, Diarrhoea

**Sodium hydroxymethanesulphinate:**
- **Species:** Rat
- **NOAEL:** 600 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 13 Weeks
- **Method:** OECD Test Guideline 408
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.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Ingestion :
Symptoms: Abdominal pain, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:
Toxicity to fish :
LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates :
EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants :
ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l
Exposure time: 72 h

Toxicity to microorganisms :
EC50: > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

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

**Benzyl alcohol:**

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 230 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 51 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

**Magnesium oxide:**

Toxicity to fish:
- LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials
### Toxicity to Daphnia and Other Aquatic Invertebrates
- **EL50** (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 48 h
- Remarks: Based on data from similar materials

### Toxicity to Algae/Aquatic Plants
- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

### Toxicity to Microorganisms
- **EC50**: > 100 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

### Sodium [2-[2,6-dichlorophenyl]amino]phenyl]acetate:

#### Toxicity to Fish
- **LC50** (Pimephales promelas (fathead minnow)): 166.6 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203

#### Toxicity to Daphnia and Other Aquatic Invertebrates
- **EC50** (Daphnia magna (Water flea)): 80.1 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

#### Toxicity to Algae/Aquatic Plants
- **EC50** (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

- **NOEC** (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

#### Toxicity to Fish (Chronic Toxicity)
- **NOEC**: 0.32 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

#### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)
- **NOEC**: 10 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

### Sodium Hydroxymethanesulphinate:

#### Toxicity to Fish
- **LC50** (Leuciscus idus (Golden orfe)): > 10,000 mg/l
- Exposure time: 96 h

#### Toxicity to Daphnia and Other Aquatic Invertebrates
- **EC50** (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms: NOEC: 10 mg/l
  Exposure time: 4 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- EC10: 8 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

**Persistence and degradability**

**Components:**

**2-Pyrrolidone:**
- Biodegradability: Result: Readily biodegradable.
- Remarks: Based on data from similar materials

**Benzyl alcohol:**
- Biodegradability: Result: Readily biodegradable.
  Biodegradation: 92 - 96 %
  Exposure time: 14 d

**Sodium hydroxymethanesulphinate:**
- Biodegradability: Result: Readily biodegradable.
  Biodegradation: 77 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301B

**Bioaccumulative potential**

**Components:**

**2-Pyrrolidone:**
- Partition coefficient: n-octanol/water: log Pow: -0.71
  Method: OECD Test Guideline 107

**Benzyl alcohol:**
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 3.1  Revision Date: 23.03.2020  SDS Number: 1313896-00010  Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

Partition coefficient: n-octanol/water

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Partition coefficient: n-octanol/water

**Sodium hydroxymethanesulphinate:**
Partition coefficient: n-octanol/water

**Mobility in soil**
No data available

**Other adverse effects**
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

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

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

IMDG-Code
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 3.1  Revision Date: 23.03.2020  SDS Number: 1313896-00010  Date of last issue: 11.12.2019

Date of first issue: 20.02.2017

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 IMO instruments
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

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 : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

ACGS - Australian Inventory of Chemical Substances; 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
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.

IN / EN