1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification

Serious eye damage/eye irritation: Category 2
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; 10</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>149-44-0</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-
vice 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

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
- Metal oxides
- Nitrogen oxides (NOx)

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal pro-
Emergency procedures: Provide personal protective equipment as required. (See section 8).

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

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

7. HANDLING AND STORAGE

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

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

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

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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**SAFETY DATA SHEET**

**Oxytetracycline / Diclofenac Liquid Formula-**

tion

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>10.10.2020</td>
<td>1313818-00011</td>
<td>23.03.2020</td>
<td>20.02.2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(Form of exposure)</th>
<th>ters / Permissible concentration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>TWA 500 µg/m³ (OEB 2) Internal</td>
<td></td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td>Wipe limit 100 µg/100 cm² Internal</td>
<td></td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>PEL (long term) (Fumes) 10 mg/m³ SG OEL</td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</td>
<td>TWA (Inhalable particulate matter) 10 mg/m³ ACGIH</td>
<td></td>
</tr>
<tr>
<td>Further information: Skin</td>
<td>Wipe limit 1000 µg/100 cm² Internal</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**

- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

**Personal protective equipment**

**Respiratory protection**

- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

  **Filter type**
  
  Combined particulates and organic vapour type

  **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.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>light brown</td>
</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>8.3 - 9.0 (as aqueous solution)</td>
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<tr>
<td>Melting point/freezing point</td>
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<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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<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>
<td>Lower explosion limit / Lower flammability limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Relative vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.05 - 1.18 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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<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>Viscosity</td>
<td>Viscosity, kinematic: 47.62 mm²/s</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

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Date of first issue: 20.02.2017

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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: > 5 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:
**SAFETY DATA SHEET**

**Oxytetracycline / Diclofenac Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

**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 tox-
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

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
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405
Magnesium oxide:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

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

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
<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxymethanesulphinate:</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
</tr>
<tr>
<td>Components:</td>
</tr>
<tr>
<td>2-Pyrroliodone:</td>
</tr>
<tr>
<td>Oxytetracycline:</td>
</tr>
</tbody>
</table>

**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-Pyrroliodone:**
- 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

**Oxytetracycline:**
- Genotoxicity in vitro: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
- 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
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| Cell type: Bone marrow |
| Application Route: Oral |
| Result: equivocal |

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

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

Benzy 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
## SAFETY DATA SHEET

### Oxytetracycline / Diclofenac Liquid Formula-

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<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Positive evidence of adverse effects on development from human epidemiological studies.</th>
</tr>
</thead>
</table>
| **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. |

### Benzyl alcohol:

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

### 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
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

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
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]phenyl]acetate:
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

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

Benzyl alcohol:
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.2  Revision Date: 10.10.2020  SDS Number: 1313818-00011  Date of last issue: 23.03.2020  Date of first issue: 20.02.2017

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
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
M-Factor (Chronic aquatic toxicity)
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

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 (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
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
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 (Pimephales promelas (fathead minnow)): 0.32 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 10 mg/l
  Exposure time: 21 d
  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 fish (Chronic toxicity):
- NOEC (Danio rerio (zebra fish)): 13.5 mg/l
  Exposure time: 35 d
  Method: OECD Test Guideline 210

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

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

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:
Partition coefficient: n-octanol/water: log Pow: 1.05

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Partition coefficient: n-octanol/water: log Pow: 4.51

Sodium hydroxymethanesulphinate:
Partition coefficient: n-octanol/water: log Pow: < 0.3

Mobility in soil
No data available

Other adverse effects
No data available
13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

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

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

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

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

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

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.2 Revision Date: 10.10.2020 SDS Number: 1313818-00011 Date of last issue: 23.03.2020 Date of first issue: 20.02.2017

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELX - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-
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.