SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Section 1: Identification

Product name: Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification

Skin sensitisation: Category 1
Reproductive toxicity: Category 1A

GHS label elements

Hazard pictograms:

Signal word: Danger
Hazard statements: H317 May cause an allergic skin reaction. H360FD May damage fertility. May damage the unborn child.

Precautionary statements

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P281 Use personal protective equipment as required.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.2
Revision Date: 10.10.2020
SDS Number: 1313817-00011
Date of last issue: 23.03.2020
Date of first issue: 20.02.2017

P308 + P313 IF exposed or concerned: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

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.

Section 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; 60</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>149-44-0</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with 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.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.2 Revision Date: 10.10.2020 SDS Number: 1313817-00011 Date of last issue: 23.03.2020 Date of first issue: 20.02.2017

Most important symptoms and effects, both acute and delayed:
- May cause an allergic skin reaction.
- 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.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media:
- None known.

Specific hazards during fire-fighting:
- 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.

Hazchem Code:
- 3Z

Section 6: Accidental release measures

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

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

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide 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.

Section 7: Handling and storage

**Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSO

**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.

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

**Conditions for safe storage**: Keep in properly 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

Section 8: Exposure controls/personal protection

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version: 2.2  Revision Date: 10.10.2020  SDS Number: 1313817-00011  Date of last issue: 23.03.2020

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>VNI</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>WES-TWA (Fumes)</td>
<td>10 mg/m³</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>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit: 1000 µg/100 cm² Internal

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

Personal protective equipment

Respiratory protection:
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Combined particulates and organic vapour type

Hand protection:
Material: Chemical-resistant gloves

Eye protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
Work uniform or laboratory coat.

Section 9: Physical and chemical properties

Appearance: liquid
Colour: light brown
Odour: No data available
Odour Threshold: No data available
pH: 8.3 - 9.0 (as aqueous solution)
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available

Date of first issue: 20.02.2017
# Section 10: Stability and reactivity

**Reactivity**
- Not classified as a reactivity hazard.

**Chemical stability**
- Stable under normal conditions.

**Possibility of hazardous reactions**
- Can react with strong oxidizing agents.

**Conditions to avoid**
- None known.

**Incompatible materials**
- Oxidizing agents.

**Hazardous decomposition products**
- No hazardous decomposition products are known.

---

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</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>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>47.62 mm²/s</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Section 11: Toxicological information

Exposure routes:
- 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:
- 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
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

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

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

**Serious eye damage/eye irritation**
Not classified based on available information.

**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
Result : negative
Remarks : Based on data from similar materials

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

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

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.

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
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

### 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>Rat</td>
<td>207 mg/kg</td>
<td>Ingestion</td>
<td>3 Months</td>
<td>No significant adverse effects were reported</td>
<td></td>
</tr>
</tbody>
</table>

### oxytetracycline:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>Rat</td>
<td>198 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>7,990 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>125 mg/kg</td>
<td>Oral</td>
<td>12 Months</td>
<td>Testis</td>
<td>Significant toxicity observed in testing</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>40 mg/kg</td>
<td>Intraperitoneal</td>
<td>14 Days</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Rat</td>
<td>1.072 mg/l</td>
<td>Inhalation (dust/mist/fume)</td>
<td>28 Days</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

### Magnesium oxide:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium oxide</td>
<td>Rat</td>
<td>&gt;= 1,000 mg/kg</td>
<td>Ingestion</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-
tion

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
Section 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

- **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
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

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
### SAFETY DATA SHEET

**Oxytetracycline / Diclofenac Liquid Formulation**

<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>1313817-00011</td>
<td>23.03.2020</td>
<td>20.02.2017</td>
</tr>
</tbody>
</table>

**aquatic invertebrates**
- 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
  - 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

**Section 13: Disposal considerations**

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

Oxytetracycline / Diclofenac Liquid Formulation

<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>1313817-00011</td>
<td>23.03.2020</td>
<td>20.02.2017</td>
</tr>
</tbody>
</table>

**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.

**National Regulations**

**NZS 5433**

- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **Hazchem Code**: 3Z

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>NZ OEL</td>
<td>New Zealand. Workplace Exposure Standards for Atmospheric Contaminants</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>NZ OEL / WES-TWA</td>
<td>Workplace Exposure Standard - Time Weighted average</td>
</tr>
</tbody>
</table>

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

NZ / EN