SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 4.2  
Revision Date: 10.10.2020  
SDS Number: 4156035-00008  
Date of last issue: 23.03.2020  
Date of first issue: 17.04.2019

**Section 1: Identification**

**Product name**: Oxytetracycline / Diclofenac 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

**Recommended use of the chemical and restrictions on use**

**Precautionary statements**

**Prevention**:  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.

**Section 2: Hazard identification**

**GHS Classification**

**Skin sensitisation**: Category 1

**Reproductive toxicity**: Category 1A

**Specific target organ toxicity - repeated exposure**: Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

**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.  
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

**Precautionary statements**

**Prevention**:  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.
### Section 3: Composition/information on ingredients

**Substance / Mixture**: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>Propylene glycol</td>
<td>57-55-6</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>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</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 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.
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<thead>
<tr>
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</tr>
</tbody>
</table>

Most important symptoms and effects, both acute and delayed:
- Rinse mouth thoroughly with water.
- May cause an allergic skin reaction.
- May damage fertility. May damage the unborn child.
- May cause damage to organs through prolonged or repeated exposure.

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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media      | None known.               |

| Specific hazards during firefighting| Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products       | Carbon oxides              |
|                                     | Chlorine compounds         |
|                                     | Nitrogen oxides (NOx)      |
|                                     | Sodium oxides              |
|                                     | Metal oxides               |

| 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. |
| Hazchem Code | Use personal protective equipment. |

### Section 6: Accidental release measures

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
</tbody>
</table>

| 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 absor- |
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Section 7: Handling and storage

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

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

Advice on safe handling: Do not get on skin or clothing. Do not breathe 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. Do not eat, drink or smoke when using this product. 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)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: DSEN

<table>
<thead>
<tr>
<th>Compound</th>
<th>Wipe limit</th>
<th>WES-TWA (particulate)</th>
<th>NZ OEL</th>
<th>WES-TWA (Vapour and particulates)</th>
<th>NZ OEL</th>
<th>TWA (Inhalable particulate matter)</th>
<th>ACGIH</th>
<th>TWA</th>
<th>NZ OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>100 µg/100 cm²</td>
<td>10 mg/m³</td>
<td>Internal</td>
<td>150 ppm</td>
<td>474 mg/m³</td>
<td>NZ OEL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1000 µg/100 cm²</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 µg/100 cm²</td>
<td>Internal</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

**Hand protection**

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**

brown, Greenish yellow

**Odour**

characteristic

**Odour Threshold**

No data available

**pH**

No data available
Melting point/freezing point : -33 °C
Initial boiling point and boiling range : 100.5 °C
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 1.15 - 1.19 (25 °C)
Density : No data available
Solubility(ies)
   Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, dynamic : 50.3 - 50.7 mPa.s (25 °C)
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

Section 10: Stability and reactivity
Reactivity : Not classified as a reactivity hazard.
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Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

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

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

Propylene glycol:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

**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 hydroxymethanesulphinylate:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

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

**oxytetracycline:**
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Remarks: No data available

Propylene glycol:
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
Remarks: Based on data from similar materials

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

Propylene glycol:
Species: Rabbit
Result: No eye irritation
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
Remarks: Based on data from similar materials
Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
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
Remarks: Based on data from similar materials

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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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.

Propylene glycol:

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
Species: CHO
Result: negative

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive
Remarks: Based on data from similar materials

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

**Carcinogenicity**
Not classified based on available information.
Components:

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

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
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.

Propylene glycol:
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

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

Test Type: Development
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
  - Remarks: Based on data from similar materials

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

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

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

**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

**Propylene glycol:**

| Species       | Rat, male |
| NOAEL         | 1,700 mg/kg |
| Application Route | Ingestion |
| Exposure time  | 2 yr |

**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: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

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, heart-burn, 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 subsipicatus (green algae)): > 500 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subsipicatus (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
Method: OECD Test Guideline 209

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Magnesium oxide:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
<table>
<thead>
<tr>
<th></th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>3 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>Exposure time: 96 h</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>Exposure time: 48 h</td>
<td>EC50 (Daphnia magna (Water flea)): 80.1 mg/l</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>Exposure time: 72 h</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>Exposure time: 32 d</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l</td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>Exposure time: 21 d</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
</tr>
<tr>
<td><strong>Sodium hydroxymethanesulphinate:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>Exposure time: 96 h</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 10,000 mg/l</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>Exposure time: 48 h</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
</tr>
</tbody>
</table>
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity):
NOEC (Danio rerio (zebra fish)): 13.5 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 5.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

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

Persistence and degradability

Components:

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

Propylene glycol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Sodium hydroxymethanesulphinate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 77 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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

Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07
octanol/water

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

Partition coefficient: n-octanol/water  
log Pow: 4.51

**Mobility in soil**

No data available

**Other adverse effects**

No data available

### Section 13: Disposal considerations

**Disposal methods**

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

### Section 14: Transport information

**International Regulations**

**UNRTDG**

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

**IATA-DGR**

- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (oxytetracycline)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **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:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy
SAFETY DATA SHEET

Oxytetracycline / Diclofenac 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>
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<td>4.2</td>
<td>10.10.2020</td>
<td>4156035-00008</td>
<td>23.03.2020</td>
<td>17.04.2019</td>
</tr>
</tbody>
</table>

ACGIH / USA. ACGIH Threshold Limit Values (TLV)
NZ OEL / New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA / 8-hour, time-weighted average
NZ OEL / WES-TWA / Workplace Exposure Standard - Time Weighted average

AICG - 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 Chemicals and Chemical Substances; IMDG - International Maritime Dangerous Goods; ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substances; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TDG - Transport of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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