SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.1  Revision Date: 23.03.2020  SDS Number: 1313805-00010  Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 91-105 Harpin Street
Bendigo 3550, Victoria Australia
Telephone: 908-740-4000
Emergency telephone number: 1 800 033 461
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 1 800 817 414

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

SECTION 2. HAZARDS 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.
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.
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. 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.
- Hazchem Code: •3Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
- Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills 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/PERSONAL PROTECTION section.
- **Local/Total ventilation**: If sufficient ventilation is unavailable, use with local exhaust ventilation.
- **Advice on safe handling**: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.
- **Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
- **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></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin sensitisation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Oxytetracycline / Diclofenac Liquid Formula-**

**Version 2.1**

**Revision Date:** 23.03.2020

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<table>
<thead>
<tr>
<th>(Fumes)</th>
<th>TWA (Inhalable particulate matter)</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

| Wipe limit | 1000 µg/100 cm² | Internal |

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**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.

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**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

**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 : No data available
Density : 1.05 - 1.18 g/cm³

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : 47.62 mm²/s

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.
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

- 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
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

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

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

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**  
**Acute oral toxicity**:  
LD50 (Rat): 55 - 240 mg/kg  
LD50 (Mouse): 170 - 389 mg/kg

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

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

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

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

**Components:**

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

**Oxytetracycline:**
**SAFETY DATA SHEET**

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<table>
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</table>

Remarks: No data available

**Benzyl alcohol:**

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

**Magnesium oxide:**

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

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

- **Result:** Irritating

**Sodium hydroxymethanesulphinate:**

- **Species:** Rat
- **Result:** No skin irritation

**Serious eye damage/eye irritation**

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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>2-Pyrrolidone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Exposure routes</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Method</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

**Oxytetracycline:**

| Test Type | Human repeat insult patch test (HRIPT) |
| Result | Sensitiser |

**Benzyl alcohol:**

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

**Magnesium oxide:**

| Test Type | Maximisation Test |
| Exposure routes | Skin contact |
| Species | Guinea pig |
| Method | OECD Test Guideline 406 |
| Result | negative |
| Remarks | Based on data from similar materials |

**Sodium hydroxymethanesulphinate:**

| Test Type | Maximisation Test |
| Exposure routes | Skin contact |
| Species | Guinea pig |
| Method | OECD Test Guideline 406 |
| Result | negative |
Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

Oxytetracycline:
Genotoxicity in vitro: Test Type: Microbial mutagenesis assay (Ames test)
Result: negative

Test Type: Mouse Lymphoma
Metabolic activation: Metabolic activation
Result: positive

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: equivocal

Test Type: Chromosomal aberration
Result: negative

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

Test Type: in vivo assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Germ cell mutagenicity -
Assessment : Weight of evidence does not support classification as a germ
cell mutagen.

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

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

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

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

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

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

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
SAFETY DATA SHEET

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</tbody>
</table>

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
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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>98 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Baboon</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Blood</td>
</tr>
<tr>
<td>Symptoms</td>
<td>constipation, Diarrhoea</td>
</tr>
</tbody>
</table>

## Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
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</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>600 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 408</td>
</tr>
</tbody>
</table>

## Aspiration toxicity

Not classified based on available information.

## Experience with human exposure

### Components:

#### Oxytetracycline:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Gastrointestinal disturbance, tooth discoloration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>May cause birth defects.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Abdominal pain, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash</th>
</tr>
</thead>
</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.1 Revision Date: 23.03.2020 SDS Number: 1313805-00010 Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

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
SAFETY DATA SHEET
Oxytetracycline / Diclofenac Liquid Formulation

Version: 2.1
Revision Date: 23.03.2020
SDS Number: 1313805-00010
Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

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
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:
EC50 (Daphnia magna (Water flea)): 80.1 mg/l
aquatic invertebrates

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:
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.1  Revision Date: 23.03.2020  SDS Number: 1313805-00010  Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-
tion

Version 2.1  Revision Date: 23.03.2020  SDS Number: 1313805-00010  Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

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

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

ADG
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

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</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

Revision Date : 23.03.2020

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-
<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>
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<tbody>
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<td>2.1</td>
<td>23.03.2020</td>
<td>1313805-00010</td>
<td>11.12.2019</td>
<td>20.02.2017</td>
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</tbody>
</table>

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.

AU / EN