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

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: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

Section 2: Hazard identification

GHS Classification
Skin sensitisation: Category 1
Reproductive toxicity: Category 1A

GHS label elements
Hazard pictograms: ![Danger]  ![Exclamation]
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.
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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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>149-44-0</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.

Most important symptoms and effects, both acute and delayed
Protection of first-aiders
Notes to physician

Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
Protection of first-aiders
Notes to physician

Section 5: Fire-fighting measures

Suitable extinguishing media
Unsuitable extinguishing media
Specific hazards during fire-fighting
Hazardous combustion products
Specific extinguishing methods
Special protective equipment for firefighters
Hazchem Code

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
Environmental precautions
Methods and materials for containment and cleaning up
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. 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>
</tbody>
</table>
Further information:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Wipe limit</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium oxide</td>
<td>100 μg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**

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

**Personal protective equipment**

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **Filter type**: Combined particulates and organic vapour type
- **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**: 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**: No data available
### 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

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### 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 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:
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<table>
<thead>
<tr>
<th>Test Method</th>
<th>Description</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>LD50 (Rat): 1,620 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
| **Acute inhalation toxicity** | LC50 (Rat): > 4.178 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403 | |

**Magnesium oxide**:

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Description</th>
<th>Data</th>
</tr>
</thead>
</table>
| **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**:

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Description</th>
<th>Data</th>
</tr>
</thead>
</table>
| **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**:

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Description</th>
<th>Data</th>
</tr>
</thead>
</table>
| **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**:

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Description</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 404</td>
<td></td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>No skin irritation</td>
<td></td>
</tr>
</tbody>
</table>
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 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

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
- **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
- **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 hydroxymethanesulphonate**:

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
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<tr>
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<th>SDS Number:</th>
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</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>

**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

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.
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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
NOAEL: >= 1,000 mg/kg
Application Route: Ingestion
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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: \( LC50 (Pimephales promelas (fathead minnow)): 460 \text{ mg/l} \)
Exposure time: 96 h

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

Toxicity to algae/aquatic plants: \( EC50 (Pseudokirchneriella subcapitata (green algae)): 770 \text{ mg/l} \)
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: \( LL50 (Pimephales promelas (fathead minnow)): > 100 \text{ mg/l} \)
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: \( EL50 (Daphnia magna (Water flea)): > 100 \text{ mg/l} \)
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: \( EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 \text{ mg/l} \)
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: \( EC50: > 100 \text{ mg/l} \)
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: \( LC50 (Pimephales promelas (fathead minnow)): 166.6 \text{ mg/l} \)
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other: \( EC50 (Daphnia magna (Water flea)): 80.1 \text{ mg/l} \)
 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.

Section 14: Transport information

International Regulations
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-tion

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

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.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-

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

Full text of other abbreviations
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

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.