SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

SECTION 1. IDENTIFICATION

Product name: Oxytetracycline / Diclofenac Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Eye irritation: Category 2B
Skin sensitization: Sub-category 1A
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure: Category 1 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H317 May cause an allergic skin reaction.
H320 Causes eye irritation.
H360FD May damage fertility. May damage the unborn child.
H372 Causes 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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of
the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>2-Pyrrolidone</td>
</tr>
<tr>
<td></td>
<td>Oxytetracycline</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Magnesium oxide</td>
</tr>
<tr>
<td></td>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxymethanesulphinate</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

### 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.
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Oxytetracycline / Diclofenac Formulation

Table:

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>10/10/2020</td>
<td>4156025-00008</td>
<td>03/23/2020</td>
<td>04/17/2019</td>
</tr>
</tbody>
</table>

In case of eye contact: Thoroughly clean shoes before reuse.

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- May cause an allergic skin reaction.
- Causes eye irritation.
- May damage fertility. May damage the unborn child.
- Causes 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

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 mist or vapors.
- 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.

Conditions for safe storage:
- Keep in properly labeled 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
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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: DSEN

<table>
<thead>
<tr>
<th>Further information:</th>
<th>Wipe limit</th>
<th>100 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>TWA (Fumes)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable fume)</td>
<td>10 mg/m³ (Magnesium)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable dust and fume)</td>
<td>3 mg/m³ (Magnesium)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>STEL (Respirable dust and fume)</td>
<td>10 mg/m³ (Magnesium)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³ (Magnesium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th>Further information:</th>
<th>Wipe limit</th>
<th>1000 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
</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 vapor 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.

**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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>brown, Greenish yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>-33 °C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>100.5 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.15 - 1.19 (25 °C)</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
### 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

**Information on likely routes of exposure**

**Inhalation**
**Skin contact**
**Ingestion**
**Eye contact**

**Acute toxicity**
Not classified based on available information.

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: > 5,000 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
### Oxytetracycline / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute toxicity (other routes of administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oxytetracycline</strong></td>
<td>LD50 (Rat): 4,800 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 2,240 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Evidence of phototoxicity was observed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Propylene glycol</strong></td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium oxide</strong></td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 423</td>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</strong></td>
<td>LD50 (Rat): 55 - 240 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 170 - 389 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 97 - 161 mg/kg</td>
<td></td>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 92 - 147 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Application Route: Intravenous

Sodium hydroxymethanesulphinate:
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:
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
Causes eye irritation.

Components:

2-Pyrrolidone:
Species   :  Rabbit
Result    :  Irritation to eyes, reversing within 7 days

Oxytetracycline:
Remarks   :  No data available
### Propylene glycol:

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

### Magnesium oxide:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

### Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Oxytetracycline:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human repeat insult patch test (HRIPT)</td>
<td>Sensitizer</td>
<td></td>
</tr>
</tbody>
</table>

#### Propylene glycol:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

#### Magnesium oxide:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximization Test</td>
</tr>
</tbody>
</table>
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Date of first issue: 04/17/2019

Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Sodium hydroxymethanesulphinate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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.

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: 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 
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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
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### Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

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

### 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 fetal development**
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: positive

### 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 fetal development**
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Oral
- Embryo-fetal toxicity.: LOAEL: 48 mg/kg body weight
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight  
Embryo-fetal toxicity: NOAEL: 1,500 mg/kg body weight  
Result: No teratogenic effects.  
Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight  
Embryo-fetal toxicity: NOAEL: 2,100 mg/kg body weight  
Result: No teratogenic effects.  
Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intramuscular  
Embryo-fetal toxicity: LOAEL: 41.5 mg/kg body weight  
Result: Postimplantation loss., No fetal abnormalities.

Test Type: Embryo-fetal development  
Species: Dog  
Application Route: Intramuscular  
Embryo-fetal 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 fetal development:  
Test Type: Embryo-fetal 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 fetal 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 fetal development**: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 5 mg/kg body weight
Result: Embryo-fetal 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
Remarks: Based on data from similar materials

**Effects on fetal development**: Test Type: Embryo-fetal 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**
Causes 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

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y
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, Diarrhea

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, Diarrhea, 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
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: ErC50 (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
Exposure time: 96 h
Remarks: Based on data from similar materials

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

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

Toxicity to microorganisms:
EC50: > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

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

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 80.1 mg/l
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
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
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
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

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. (oxtetracycline)
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**

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**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation**

**TDG**

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<td>III</td>
<td>9</td>
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**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**

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

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<th>AICS</th>
<th>DSL</th>
<th>IECSC</th>
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</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA BC OEL / STEL : short-term exposure limit
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWA : Time-weighted average exposure value

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