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: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASETWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

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.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

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

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>No data available</td>
<td>616-45-5</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>No data available</td>
<td>79-57-2</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>&gt;= 5 - &lt; 10 *</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>Caustic magnesite</td>
<td>1309-48-4</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Sodium[2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>No data available</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Sodium hydroxyethanesulphinate</td>
<td>Methanesulfonic acid, hydroxy-, monosodium salt, dihydrate</td>
<td>6035-47-8</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

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

SECTION 4. FIRST AID MEASURES
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

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

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

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. 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

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
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

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 Self-reactive substances and mixtures 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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>TWA (Fumes)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fume)</td>
<td>10 mg/m³ (Magnesium)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<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></td>
<td>STEL (Respirable dust and fume)</td>
<td>10 mg/m³ (Magnesium)</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Inhalable dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</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 vapor type

Hand protection
- Material: Chemical-resistant gloves
### SAFETY DATA SHEET

**Oxytetracycline / Diclofenac Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>4.8</td>
<td>04/04/2023</td>
<td>4156025-00014</td>
<td>10/01/2022</td>
<td>04/17/2019</td>
</tr>
</tbody>
</table>

#### 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>
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</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>
</tbody>
</table>
Relative density : 1.15 - 1.19 (25 °C)
Density : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : 50.3 - 50.7 mPa.s (25 °C)
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
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: > 2,000 mg/kg
Method : Calculation method
Components:

2-Pyrrolidone:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 401
  Assessment: The substance or mixture has no acute oral toxicity
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

Oxytetracycline:
- Acute oral toxicity: LD50 (Rat): 4,800 mg/kg
  LD50 (Mouse): 2,240 mg/kg
  Remarks: Evidence of phototoxicity was observed
- Acute inhalation toxicity: No data available
- Acute dermal toxicity: No data available
- Acute toxicity (other routes of administration): LD50 (Rat): 4,840 mg/kg
  Application Route: Intramuscular
  LD50 (Mouse): 3,500 mg/kg
  Application Route: Subcutaneous

Propylene glycol:
- Acute oral toxicity: LD50 (Rat): 22,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 44.9 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Magnesium oxide:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity
  Remarks: Based on data from similar materials
- Acute inhalation toxicity: LC50 (Rat): > 2.1 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
  Remarks: Based on data from similar materials
Sodium [2-[2,6-dichlorophenyl]amino]phenyl]acetate:
Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg

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

Sodium hydroxymethanesulphonate:
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 hydroxymethanesulphonate:
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:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Magnesium oxide:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Result : Mild eye irritation

Sodium hydroxymethanesulphinate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

2-Pyrrolidone:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : 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 : Sensitizer
Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Magnesium oxide:
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

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
SAFETY DATA SHEET

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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

  - 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
    - 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>104 weeks</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>103 weeks</td>
<td>equivocal</td>
<td></td>
</tr>
</tbody>
</table>

**Target Organs:** Adrenal gland, Pituitary gland
- **Remarks:** The mechanism or mode of action may not be relevant in humans.
Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

**Propylene glycol:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

**Magnesium oxide:**
- **Species:** Mouse
- **Application Route:** Ingestion
- **Exposure time:** 96 weeks
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
- **Species:** Rat
- **Application Route:** Oral
- **Exposure time:** 2 Years
- **Result:** negative
- **Species:** Mouse
- **Application Route:** Oral
- **Exposure time:** 2 Years
- **Result:** negative

**Reproductive toxicity**
May damage fertility. May damage the unborn child.

**Components:**

**2-Pyrrolidone:**
- **Effects on fertility:** Test Type: One-generation reproduction toxicity study. Species: Rat. Application Route: Ingestion. Result: positive. Remarks: Based on data from similar materials

**Effects on fetal development:** Test Type: Embryo-fetal 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 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:
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on 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

  - Species: Rat
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>4.8</td>
<td>04/04/2023</td>
<td>4156025-00014</td>
<td>10/01/2022</td>
<td>04/17/2019</td>
</tr>
</tbody>
</table>

NOAEL : 40 mg/kg  
LOAEL : 100 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 14 Days  
Target Organs : Kidney

**Propylene glycol:**
Species : Rat, male  
NOAEL : >= 1,700 mg/kg  
Application Route : Ingestion  
Exposure time : 2 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Toxicity to microorganisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>EC50: 17.9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
<td>NOEC: 0.2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
<td>NOEC: 0.2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
<td>NOEC: 0.2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
<td>NOEC: 0.2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
<td>NOEC: 0.2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h</td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
<td>NOEC (Pseudomonas putida): &gt; 20,000 mg/l Exposure time: 18 h</td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
<td></td>
<td></td>
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</table>
### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Test</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>80.1 mg/l</td>
<td>48 h</td>
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</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
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<tbody>
<tr>
<td></td>
<td>71.9 mg/l</td>
<td>72 h</td>
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<tr>
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<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
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<tbody>
<tr>
<td></td>
<td>49.2 mg/l</td>
<td>72 h</td>
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### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Test</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
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<th>Notes</th>
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<tbody>
<tr>
<td></td>
<td>0.32 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
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</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Test</th>
<th>NOEC (Daphnia magna (Water flea))</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
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### Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Test</th>
<th>Test</th>
<th>EC50 (Leuciscus idus (Golden orfe))</th>
<th>Exposure time</th>
<th>Method</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>&gt; 10,000 mg/l</td>
<td>96 h</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Test</th>
<th>EC50 (Daphnia magna (Water flea))</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Test</th>
<th>ErC50 (Desmodesmus subspicatus (green algae))</th>
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<tr>
<td></td>
<td></td>
<td>370 mg/l</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Test</th>
<th>NOEC (Danio rerio (zebra fish))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>13.5 mg/l</td>
<td>35 d</td>
<td>OECD Test Guideline 210</td>
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<th>Test</th>
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<th>Exposure time</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>5.6 mg/l</td>
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<table>
<thead>
<tr>
<th>Test</th>
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<tr>
<td></td>
<td></td>
<td>&gt; 1,000 mg/l</td>
<td>4 h</td>
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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 dMethod: OECD Test Guideline 301F

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

Bioaccumulative potential

Components:

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

Propylene glycol:

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.Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.If not otherwise specified: Dispose of as unused product.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

SECTION 14. TRANSPORT INFORMATION

International Regulations

<table>
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<td>Proper shipping name :</td>
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<td>Packing group :</td>
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<td>Labels :</td>
<td>9</td>
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<tr>
<td>EmS Code :</td>
<td>F-A, S-F</td>
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<td>Marine pollutant :</td>
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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>Proper shipping name :</td>
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<td>Marine pollutant :</td>
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</table>

**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.
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:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations:

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- CA AB OEL: Canada, Alberta, Occupational Health and Safety Code (table 2; OEL)
- 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 / TWAEV: Time-weighted average exposure value

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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 4.8  Revision Date: 04/04/2023  SDS Number: 4156025-00014  Date of last issue: 10/01/2022

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.

CA / Z8