SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Oxytetracycline / Diclofenac Formulation

**Manufacturer or supplier’s details**

**Company**: MSD

**Address**: Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

**Telephone**: 908-740-4000

**Emergency telephone**: 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. HAZARDS IDENTIFICATION

**GHS Classification in accordance with ABNT NBR 14725 Standard**

- **Skin irritation**: Category 3
- **Eye irritation**: Category 2B
- **Skin sensitization**: Category 1
- **Reproductive toxicity**: Category 1A
- **Specific target organ toxicity - repeated exposure**: Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
- **Short-term (acute) aquatic hazard**: Category 1
- **Long-term (chronic) aquatic hazard**: Category 1

**GHS label elements in accordance with ABNT NBR 14725 Standard**

- **Hazard pictograms**
- **Signal Word**: Danger
- **Hazard Statements**: H316 Causes mild skin irritation.
Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P264 Wash skin thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

Other hazards which do not result in classification:
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>Eye irritation, Category 2B, Reproductive toxicity, Category 1B</td>
<td>&gt;= 50 - &lt; 70</td>
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<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>Skin sensitization, Sub-category 1A, Reproductive toxicity, Category 1A, Short-term (acute) aquatic hazard, Category 1, Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>Acute toxicity (Oral), Category 3, Skin irritation, Category 2, Eye irritation, Category 2B, Reproductive toxicity, Category 2</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Oxytetracycline / Diclofenac Formulation

Specific target organ toxicity - repeated exposure (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate), Category 1
Short-term (acute) aquatic hazard, Category 3
Long-term (chronic) aquatic hazard, Category 2

Sodium hydroxymethanesulphinate 6035-47-8 Germ cell mutagenicity, Category 2 Reproductive toxicity, Category 2 >= 0,1 <= 1

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

Most important symptoms and effects, both acute and delayed: Causes mild skin irritation. May cause an allergic skin reaction. Causes eye irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant 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 vapors or spray mist.
- Do not swallow.
- Do not get in eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

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 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>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</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>
</tbody>
</table>

Further information: Skin sensitization

- Wipe limit | 100 µg/100 cm² | Internal

Further information: Skin

- Wipe limit | 1000 µg/100 cm² | Internal
Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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

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 face shield 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

Color: brown, Greenish yellow

Odor: characteristic

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: -33 °C

Initial boiling point and boiling range: 100,5 °C

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 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
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

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
SAFETY DATA SHEET

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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**

Causes mild skin irritation.

**Components:**

**2-Pyrrolidone:**

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

**Oxytetracycline:**

- **Remarks**: No data available

**Magnesium oxide:**

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

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

- **Result**: Irritating

**Sodium hydroxymethanesulphinate:**

- **Species**: Rat  
  **Remarks**: 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
**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>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>23.03.2020</td>
<td>4156026-00007</td>
<td>11.12.2019</td>
<td>17.04.2019</td>
</tr>
</tbody>
</table>

- **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

**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
Germ cell mutagenicity
Not classified based on available information.

Components:

2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative</td>
</tr>
</tbody>
</table>

| 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:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Microbial mutagenesis assay (Ames test) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Mouse Lymphoma Metabolic activation: Metabolic activation Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: equivocal</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: equivocal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: in vivo assay Species: Mouse Application Route: Intraperitoneal injection Result: negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity - Weight of evidence does not support classification as a germ
Assessment

**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

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

Genotoxicity in vitro
- 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

Genotoxicity in vivo
- Test Type: Mouse Lymphoma
  - 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

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

### 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:
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
Reproductive toxicity - Assessment

Skeletal and visceral variations., Postimplantation loss.

Positive evidence of adverse effects on development from human epidemiological studies.

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

### Components:

#### Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
- **Target Organs:** Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

#### 2-Pyrrolidone:
- **Species:** Rat
- **NOAEL:** 207 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 3 Months
- **Method:** OECD Test Guideline 408

#### Oxytetracycline:
- **Species:** Rat
- **LOAEL:** 198 mg/kg
- **Application Route:** Oral
- **Exposure time:** 13 Weeks
- **Target Organs:** Bone
- **Remarks:** No significant adverse effects were reported

#### Species:
- **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:
- **Species:** Dog
- **LOAEL:** 125 mg/kg
- **Application Route:** Oral
- **LOAEL:** 250 mg/kg
- **Application Route:** Oral
<table>
<thead>
<tr>
<th>Exposure time</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Testis</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

**Magnesium oxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 1.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 407</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
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<tbody>
<tr>
<td>NOAEL</td>
<td>600 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 408</td>
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<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
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</table>

**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
M-Factor (Acute aquatic toxicity): 10

M-Factor (Chronic aquatic toxicity): 10

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

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 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
- 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

#### 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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Partition coefficient: n-octanol/water: log Pow: 4.51

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Oxytetracycline)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
## SAFETY DATA SHEET

### Oxytetracycline / Diclofenac Formulation

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<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>23.03.2020</td>
<td>4156026-00007</td>
<td>11.12.2019</td>
<td>17.04.2019</td>
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</table>

### Class
- 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.

### Domestic regulation

**ANTT**
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)
- Class: 9
- Packing group: III
- Labels: 9
- Hazard Identification Number: 90

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### SECTION 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

- National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

- Brazil. List of chemicals controlled by the Federal Police: Not applicable

**International Regulations**

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

### SECTION 16. OTHER INFORMATION

**Further information**
- Sources of key data used to: Internal technical data, data from raw material SDSs, OECD

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

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

BR / Z8