SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Liquid 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
Eye irritation : Category 2A
Skin sensitization : Category 1
Reproductive toxicity : Category 1A
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 : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.
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**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**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, Reproductive toxicity, Category 2B</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>Skin sensitization, Sub-category 1A Reproductive toxicity, Category 1A</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short-term (acute) aquatic hazard, Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>Acute toxicity (Oral), Category 4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity (Inhalation), Category 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2A</td>
<td></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-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>Acute toxicity (Oral), Category 3</td>
<td>&gt;= 0,25 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin irritation, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 2B</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-
tion

Version 3.1  Revision Date: 23.03.2020  SDS Number: 1313803-00010  Date of last issue: 11.12.2019
Date of first issue: 20.02.2017

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

Sodium hydroxymethanesul-
phinate  149-44-0  Germ cell mutagenici-
ty, Category 2
Reproductive toxicity,
Category 2

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

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

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

Notes to physician : Treat symptomatically and supportively.

SECTION 5. 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
   Metal oxides
   Nitrogen oxides (NOx)
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
   Use water spray to cool unopened containers.
   Remove undamaged containers from fire area if it is safe to do so.
   Evacuate area.
Special protective equipment for 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-dichloro-phenyl)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></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin sensitization

Wipe limit 100 µg/100 cm² Internal

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 faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection: Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: light brown
Odor: No data available
Odor Threshold: No data available
pH: 8.3 - 9.0 (as aqueous solution)
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid 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>
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<tr>
<td>3.1</td>
<td>23.03.2020</td>
<td>1313803-00010</td>
<td>11.12.2019</td>
<td>20.02.2017</td>
</tr>
</tbody>
</table>

flammability limit

Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : 1,05 - 1,18 g/cm³

Solubility(ies)
Water solubility : soluble

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

Viscosity
Viscosity, kinematic : 47,62 mm²/s

Explosive properties : Not explosive

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
                                          Skin contact
                                          Ingestion
                                          Eye contact

Acute toxicity
Not classified based on available information.

Product:
SAFETY DATA SHEET
Oxytetracycline / Diclofenac Liquid Formula-

Version 3.1  Revision Date: 23.03.2020  SDS Number: 1313803-00010  Date of last issue: 11.12.2019  Date of first issue: 20.02.2017

Acute oral toxicity
: Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Acute inhalation toxicity
: Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

2-Pyrrolidone:
Acute oral toxicity
: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity
: LD50 (Rabbit): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Oxytetracycline:
Acute oral toxicity
: LD50 (Rat): 4.800 mg/kg
LD50 (Mouse): 2.240 mg/kg
Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity
: Remarks: No data available

Acute dermal toxicity
: Remarks: No data available

Acute toxicity (other routes of administration)
: LD50 (Rat): 4.840 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 3.500 mg/kg
Application Route: Subcutaneous

Benzyl alcohol:
Acute oral toxicity
: LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity
: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Magnesium oxide:
Acute oral toxicity
: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute inhalation toxicity: LC50 (Rat): > 2.1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Acute oral toxicity: LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous
LD50 (Mouse): 92 - 147 mg/kg
Application Route: Intravenous

Sodium hydroxymethanesulphinate:
Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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

Components:

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

Oxytetracycline:
Remarks: No data available

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

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

Sodium hydroxymethanesulphinate:
Species : Rat
Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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

Oxytetracycline:
Remarks : No data available

Benzyl alcohol:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

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

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

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

Respiratory or skin 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

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
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

Germ cell mutagenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
**Genotoxicity in vitro**

**Oxytetracycline:**
- 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:**
- Test Type: Microbial mutagenesis assay (Ames test)
  - Result: negative

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

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

- Test Type: Chromosomal aberration
  - Result: negative

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

- Test Type: in vivo assay
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Result: negative

**Germ cell mutagenicity - Assessment**:
- Weight of evidence does not support classification as a germ cell mutagen.

**Benzyl alcohol:**
- 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

Genotoxicity in vivo:

- **Test Type:** Chromosomal aberration
  - Species: CHO
  - Result: negative

**Sodium hydroxymethanesulphinate:**

Genotoxicity in vitro:

- **Test Type:** Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative

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

Genotoxicity in vivo:

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

- **Germ cell mutagenicity - Assessment**
  - Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

**Carcinogenicity**

Not classified based on available information.

**Components:**

**2-Pyrrolidone:**

- **Species:** Mouse
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<table>
<thead>
<tr>
<th>Application Route</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>18 month(s)</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Oxytetracycline:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</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

Benzyl alcohol:

<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>103 weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 451</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

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

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.
  Remarks: 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
  Result: Postimplantation loss.
  Skeletal malformations.

  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.

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on 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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

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

Repeated dose toxicity

Components:

2-Pyrrolidone:
Species : Rat
NOAEL : 207 mg/kg
Application Route : Ingestion
Exposure time : 3 Months
Method : OECD Test Guideline 408
Oxytetracycline:
Species: Rat
LOAEL: 198 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Mouse
LOAEL: 7,990 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 125 mg/kg
LOAEL: 250 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Testis
Remarks: Significant toxicity observed in testing

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

Benzyl alcohol:
Species: Rat
NOAEL: 1,072 mg/l
Application Route: Inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Magnesium oxide:
Species: Rat
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
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 3.1  Revision Date: 23.03.2020  SDS Number: 1313803-00010  Date of last issue: 11.12.2019  Date of first issue: 20.02.2017

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

Species: Rat
NOAEL: 600 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 408

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Oxytetracycline:
Ingestion:
Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Ingestion:
Symptoms: Abdominal pain, 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
### Oxytetracycline / Diclofenac Liquid Formulation

#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC10 (Desmodesmus subspicatus)</td>
<td>&gt; 1,000 mg/l</td>
<td>30 min</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

#### Oxytetracycline:

- **Toxicity to fish**
  - LC50 (Oryzias latipes): 110 mg/l
  - OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna): 621 mg/l
  - Method: OECD Test Guideline 202
  - EC50 (Daphnia magna): 669 mg/l
  - Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants**
  - EC50 (Anabaena): 0,032 mg/l
  - OECD Test Guideline 209
  - 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
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - NOEC: 0,2 mg/l
  - Exposure time: 3 h

#### Benzyl alcohol:

- **Toxicity to fish**
  - LC50 (Pimephales promelas): 460 mg/l
  - Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna): 230 mg/l
  - Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants**
  - EC50 (Pseudokirchneriella subcapitata): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Magnesium oxide:

Toxicity to fish:
LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

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

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

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

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

Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other 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

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

- NOEC (Danio rerio (zebra fish)): 13,5 mg/l
  Exposure time: 35 d
  Method: OECD Test Guideline 210

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

- EC10 (Daphnia magna (Water flea)): 8 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Toxicity to microorganisms:

- NOEC: 10 mg/l
  Exposure time: 4 h

**Persistence and degradability**

**Components:**

**2-Pyrrolidone:**

Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

**Benzyl alcohol:**

Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

**Sodium hydroxymethanesulphinate:**

Biodegradability: Result: Readily biodegradable.
Biodegradation: 77 %
Bioaccumulative potential

Components:

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

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1.05

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

Sodium hydroxymethanesulphinate:
Partition coefficient: n-octanol/water: log Pow: < 0.3

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

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.
### SAFETY DATA SHEET

**Oxytetracycline / Diclofenac Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
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<td>11.12.2019</td>
<td>20.02.2017</td>
</tr>
</tbody>
</table>

- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (passenger aircraft)**: 964
- **Environmentally hazardous**: yes

**IMDG-Code**

- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)

**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)

**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


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International 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; 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.

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