1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation : Category 2
Skin sensitisation : 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
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.
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or.
repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

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 vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ 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 advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>
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: May cause an allergic skin reaction. Causes serious 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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
6. ACCIDENTAL RELEASE MEASURES

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

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

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

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 vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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 labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types: Strong oxidizing agents.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</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></td>
<td></td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>PEL (long term) (Fumes)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TWA (Inhalable particulate matter)</td>
<td></td>
<td></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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures

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

Personal protective equipment

Respiratory protection

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type

Combined particulates and organic vapour type

Hand protection

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.

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
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>Colour</td>
<td>brown, Greenish yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>-33 °C</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>100.5 °C</td>
</tr>
<tr>
<td>range</td>
<td></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</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.15 - 1.19 (25 °C)</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>50.3 - 50.7 mPa.s (25 °C)</td>
</tr>
</tbody>
</table>
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

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.

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: 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
  Application Route: Intravenous

Sodium hydroxymethanesulphinate:

Acute oral toxicity:
- LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 423
  Remarks: Based on data from similar materials

Acute dermal toxicity:
- LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

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

**Oxytetracycline:**
Remarks: No data available

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

**Sodium hydroxymethanesulphinate:**
Species: Rat
Result: No skin irritation
Remarks: Based on data from similar materials

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

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

**Oxytetracycline:**
Remarks: No data available

**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 sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

**Respiratory sensitisation**
Not classified based on available information.
Components:

2-Pyrrolidone:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Oxytetracycline:
Test Type : Human repeat insult patch test (HRIPT)
Result : Sensitiser

Magnesium oxide:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Sodium hydroxymethanesulphinate:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
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
oxytetracycline:
Genotoxicity in vitro
: Test Type: Microbial mutagenesis assay (Ames test)
  Result: negative

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

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

  Test Type: Chromosomal aberration
  Result: negative

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

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

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

Magnesium oxide:
Genotoxicity in vitro
: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

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

  Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Genotoxicity in vitro
: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

  Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo:  Test Type: Chromosomal aberration
Species: CHO
Result: negative

Sodium hydroxymethanesulphinate:
Genotoxicity in vitro:  Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive
Remarks: Based on data from similar materials

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

Carcinogenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
Species: Mouse
Application Route: Ingestion
Exposure time: 18 month(s)
Result: negative
Remarks: Based on data from similar materials

Oxytetracycline:
Species: Mouse
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 103 weeks
Result: equivocal
Target Organs: Adrenal gland, Pituitary gland
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen
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 foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments. Clear evidence of adverse effects on development, based on animal experiments.

Oxytetracycline:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations
Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

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

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

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

Magnesium oxide:
Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility
Effects on foetal development:

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

- **Test Type:** Development
- **Species:** Rabbit
- **Application Route:** Oral
- **Developmental Toxicity:** LOAEL: 5 mg/kg body weight
- **Result:** Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment:

Suspected of damaging the unborn child.

**Sodium hydroxymethanesulphinate:***

**Effects on fertility**:

- **Test Type:** Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- **Species:** Rat
- **Application Route:** Ingestion
- **Method:** OECD Test Guideline 422
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Effects on foetal development**:

- **Test Type:** Embryo-foetal 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     | 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      |

**Magnesium oxide:**

| Species     | Rat          |
| LOAEL       | >= 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, Diarrhoea

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, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

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
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 4.2
Revision Date: 10.10.2020
SDS Number: 4156036-00008
Date of last issue: 23.03.2020
Date of first issue: 17.04.2019

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:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 10,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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 : NOEC (Daphnia magna (Water flea)): 5.6 mg/l
10.10.2020

aquatic invertebrates (Chronic Toxicity)
Exposure time: 21 d
Method: OECD Test Guideline 211
Remark: Based on data from similar materials

Toxicity to microorganisms
EC50: > 1,000 mg/l
Exposure time: 4 h
Remark: Based on data from similar materials

Persistence and degradability

Components:

2-Pyrrolidone:
Biodegradability
Result: Readily biodegradable.
Remark: Based on data from similar materials

Sodium hydroxymethanesulphinate:
Biodegradability
Result: Readily biodegradable.
Biodegradation: 77%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remark: 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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
Dispose 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.

14. TRANSPORT INFORMATION

International Regulations
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 4.2  Revision Date: 10.10.2020  SDS Number: 4156036-00008  Date of last issue: 23.03.2020  Date of first issue: 17.04.2019

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

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

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials): Not applicable
16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
SG OEL: Singapore, Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA: 8-hour, time-weighted average
SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term

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

Oxytetracycline / Diclofenac Formulation

Version 4.2
Revision Date: 10.10.2020
SDS Number: 4156036-00008
Date of last issue: 23.03.2020
Date of first issue: 17.04.2019

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.

SG / EN