SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline / Diclofenac Formulation

Manufacturer or supplier's details
Company : MSD
Address : 91-105 Harpin Street
          Bendigo 3550, Victoria Australia
Telephone : +1-908-740-4000
Emergency telephone number : 1 800 033 461
E-mail address : EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms : [Images of hazard symbols]
Signal word : Danger
Hazard statements : H317 May cause an allergic skin reaction.
                  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.

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.
                           P272 Contaminated work clothing should not be allowed out of the workplace.
                           P280 Wear protective gloves.
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version: 4.2  Revision Date: 10.10.2020  SDS Number: 4156027-00008  Date of last issue: 23.03.2020  Date of first issue: 17.04.2019

P281 Use personal protective equipment as required.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P333 + P313 IF skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

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.

SECTION 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;= 30 - &lt; 60</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Sodium hydroxyxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

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.
### SECTION 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.

**Hazchem Code**
- •3Z

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

**Methods and materials for containment and cleaning up**
- Soak up with inert absorbent material.
- For large spills, provide 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 absor-
bent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing.
Do not breathe mist or 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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
### Further information: DSEN

<table>
<thead>
<tr>
<th>Substance</th>
<th>Wipe limit</th>
<th>TWA (particulate)</th>
<th>TWA (Total (vapour and particles))</th>
<th>TWA (Inhalable particulate matter)</th>
<th>TWA (Inhalable particulate matter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>100 µg/100 cm²</td>
<td>10 mg/m³</td>
<td>150 ppm 474 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1000 µg/100 cm²</td>
<td>100 µg/m³</td>
<td>100 µg/m³ (OEB 2)</td>
<td>100 µg/m³ (OEB 2)</td>
<td>100 µg/m³ (OEB 2)</td>
</tr>
</tbody>
</table>

### 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**
- 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
- **Colour**: brown, Greenish yellow
- **Odour**: characteristic
- **Odour Threshold**: No data available
- **pH**: No data available
SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
### SECTION 11. TOXICOLOGICAL INFORMATION

**Exposure routes:**
- 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
- **Acute inhalation toxicity:** Remarks: Evidence of phototoxicity was observed
- **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

**Propylene glycol:**
- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
### 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>4.2</td>
<td>10.10.2020</td>
<td>4156027-00008</td>
<td>23.03.2020</td>
<td>17.04.2019</td>
</tr>
</tbody>
</table>

#### Acute inhalation toxicity
- **LC50 (Rabbit):** > 159 mg/l  
  - Exposure time: 4 h  
  - Test atmosphere: dust/mist

#### Acute dermal toxicity
- **LD50 (Rabbit):** > 2,000 mg/kg  
  - Assessment: The substance or mixture has no acute dermal toxicity

#### Magnesium oxide:
- **Acute oral toxicity**  
  - **LD50 (Rat):** > 2,000 mg/kg  
    - Method: OECD Test Guideline 423  
    - Assessment: The substance or mixture has no acute oral toxicity  
    - Remarks: Based on data from similar materials

- **Acute inhalation toxicity**  
  - **LC50 (Rat):** > 2.1 mg/l  
    - Exposure time: 4 h  
    - Test atmosphere: dust/mist  
    - Method: OECD Test Guideline 403  
    - Remarks: Based on data from similar materials

#### Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
- **Acute oral toxicity**  
  - **LD50 (Rat):** 55 - 240 mg/kg  
    - **LD50 (Mouse):** 170 - 389 mg/kg

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

#### Sodium 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:**
**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>4.2</td>
<td>10.10.2020</td>
<td>4156027-00008</td>
<td>23.03.2020</td>
<td>17.04.2019</td>
</tr>
</tbody>
</table>

**Remarks**: No data available

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

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

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

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components**:

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

**oxytetracycline**:
- **Remarks**: No data available

**Propylene glycol**:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405

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

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

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

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Oxytetracycline:</th>
<th>Genotoxicity in vitro</th>
<th>Germ cell mutagenicity - Assessment</th>
<th>Propylene glycol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Result: negative</td>
<td>Test Type: Microbial mutagenesis assay (Ames test)</td>
<td>Result: negative</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: negative</td>
<td>Test Type: Mouse Lymphoma</td>
<td>Result: positive</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Mouse lymphoma</td>
<td>Test Type: sister chromatid exchange assay</td>
<td>Method: Metabolic activation: Metabolic activation</td>
<td>Result: equivocal</td>
<td></td>
</tr>
<tr>
<td>Test System: Chinese hamster ovary cells</td>
<td>Test Type: Chromosomal aberration</td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test</td>
<td>Test Type: in vivo assay</td>
<td>Result: equivocal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: equivocal</td>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Micronucleus test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: equivocal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: in vivo assay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Intraperitoneal injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(in vivo cytogenetic assay)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Application Route: Intraperitoneal injection
Result: negative

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

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

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

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

Test Type: Mouse Lymphoma
Result: negative

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

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

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

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

**Carcinogenicity**
Not classified based on available information.
Components:

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

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

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

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

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

Magnesium oxide:
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:
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.

Propylene glycol:
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal 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 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

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

### Species

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

### Species

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

### Species

| Species       |  |  |
|---------------|---------------|
| NOAEL         | | |
| LOAEL         | 250 mg/kg     |
| Application Route | Oral          |
| Exposure time  | 12 Months     |
| Target Organs  | Testis        |
| Remarks        | No significant adverse effects were reported |

### Species

| Species       |  |  |
|---------------|---------------|
| NOAEL         | 100 mg/kg     |
| Application Route | Intrapertoneal |
| Exposure time  | 14 Days       |
| Target Organs  | Kidney        |
| Remarks        | Significant toxicity observed in testing |

### Propylene glycol:

| Species       |  |  |
|---------------|---------------|
| NOAEL         | | |
| Application Route | Oral          |
| Exposure time  | 2 yr          |
| Target Organs  | Kidney        |
| Remarks        | | |

### Magnesium oxide:

| Species       |  |  |
|---------------|---------------|
| NOAEL         | 40 mg/kg      |
| Application Route | Ingestion    |
| Exposure time  | 28 Days       |
| Remarks        | Based on data from similar materials |

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

| Species       |  |  |
|---------------|---------------|
| NOAEL         | 0.25 mg/kg    |
| Application Route | Oral          |
| Exposure time  | 98 w          |
| Target Organs  | Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate |
| Remarks        | | |

| Species       |  |  |
|---------------|---------------|
| NOAEL         | | |
| 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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l
Exposure time: 72 h
Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

**oxytetracycline:**

Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Daphnia magna (Water flea)): 621 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

EC50 (Anabaena): 0.032 mg/l
Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l
Exposure time: 72 h

Toxicity to microorganisms:

EC50: 17.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 0.2 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Propylene glycol:**

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

**Magnesium oxide:**

Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
## Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Daphnia magna (Water flea)</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

## Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>&gt; 100 mg/l</td>
<td>72 h</td>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

## Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>&gt; 100 mg/l</td>
<td>3 h</td>
<td></td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

## Toxicity to fish

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>166.6 mg/l</td>
<td>96 h</td>
<td>Pimephales promelas (fathead minnow)</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

## Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>80.1 mg/l</td>
<td>48 h</td>
<td>Daphnia magna (Water flea)</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

## Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>71.9 mg/l</td>
<td>72 h</td>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>OECD Test Guideline 201</td>
<td>NOEC: 49.2 mg/l</td>
</tr>
</tbody>
</table>

## Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>0.32 mg/l</td>
<td>32 d</td>
<td>Pimephales promelas (fathead minnow)</td>
<td>OECD Test Guideline 210</td>
<td>NOEC: 10 mg/l</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Daphnia magna (Water flea)</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

## Sodium hydroxymethanesulphinate

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>&gt; 10,000 mg/l</td>
<td>96 h</td>
<td>Leuciscus idus (Golden orfe)</td>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201
   Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC (Danio rerio (zebra fish)): 13.5 mg/l
   Exposure time: 35 d
   Method: OECD Test Guideline 210
   Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 5.6 mg/l
   Exposure time: 21 d
   Method: OECD Test Guideline 211
   Remarks: Based on data from similar materials

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

Persistence and degradability

Components:

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

Propylene glycol:
   Biodegradability: Result: Readily biodegradable.
   Biodegradation: 98.3 %
   Exposure time: 28 d
   Method: OECD Test Guideline 301F

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

Bioaccumulative potential

Components:

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

Propylene glycol:
   Partition coefficient: n-octanol/water: log Pow: -1.07
octanol/water

**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, 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.

National Regulations

ADG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z

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

Prohibition/Licensing Requirements :

There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 10.10.2020

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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.

AU / EN