SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline / Diclofenac Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Oxytetracycline / Diclofenac Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2
Skin sensitisation, Category 1
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

H319: Causes serious eye irritation.
H317: May cause an allergic skin reaction.
H360FD: May damage fertility. May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms: [Images]
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 through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
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.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Oxytetracycline
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<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>616-45-5 210-483-1</td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2 201-212-8</td>
<td>Skin Sens. 1A; H317 Repr. 1A; H360D</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-</td>
<td>15307-79-6 239-346-4</td>
<td>Acute Tox. 3; H301 Skin Irrit. 2; H315</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.
6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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 vapours 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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents, Organic peroxides, Explosives.
## Gases

### 7.3 Specific end use(s)

**Specific use(s)**: No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Oxytetracycline</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Magnesium oxide</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit 1000 µg/100 cm² Internal

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### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57.8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
</tr>
</tbody>
</table>
Consumers  
**Inhalation** | Long-term systemic effects | 17.1 mg/m³
---|---|---
Consumers  
**Skin contact** | Long-term systemic effects | 6 mg/kg bw/day
Consumers  
**Skin contact** | Acute systemic effects | 167 mg/kg bw/day
Consumers  
**Ingestion** | Long-term systemic effects | 5.2 mg/kg bw/day
Consumers  
**Ingestion** | Acute systemic effects | 33.3 mg/kg bw/day

**Propylene glycol**

Workers  
**Inhalation** | Long-term local effects | 10 mg/m³
Workers  
**Inhalation** | Long-term systemic effects | 168 mg/m³
Consumers  
**Inhalation** | Long-term local effects | 10 mg/m³
Consumers  
**Inhalation** | Long-term systemic effects | 50 mg/m³

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.05 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.4205 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0612 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**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**

**Eye protection**

Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**
Material : Chemical-resistant gloves
Skin and body protection : Work uniform or laboratory coat.
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387
Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : brown, Greenish yellow
Odour : characteristic
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : -33 °C
Initial boiling point and boiling range : 100.5 °C
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 1.15 - 1.19 (25 °C)
Density : No data available
Solubility(ies) : Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Viscosity, dynamic : 50.3 - 50.7 mPa.s (25 °C)
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids): No data available
- Molecular weight: No data available
- Particle size: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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

### 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

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

Sodium hydroxymethanesulphinate:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
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.
## Oxytetracycline / Diclofenac Formulation

### Components:

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Oxytetracycline:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human repeat insult patch test (HRIPT)</td>
<td>OECD Test Guideline 429</td>
<td>Sensitiser</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Sodium hydroxymethanesulphinate:

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<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
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<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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<tr>
<th>Genotoxicity in vitro</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td></td>
<td>Chromosome aberration test in vitro</td>
<td>OECD Test Guideline 473</td>
<td>negative</td>
<td>Based on data from similar materials</td>
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</table>

#### Oxytetracycline:

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</tr>
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<tbody>
<tr>
<td></td>
<td>Microbial mutagenesis assay (Ames test)</td>
<td>OECD Test Guideline 474</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

---

**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Oxytetracycline / Diclofenac Formulation**

**Components:**

**2-Pyrrolidone:**

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<tr>
<th>Test Type</th>
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**Components:**

**2-Pyrrolidone:**

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</tbody>
</table>
**Oxytetracycline / Diclofenac Formulation**

<table>
<thead>
<tr>
<th>Test Type: Mouse Lymphoma</th>
<th>Metabolic activation: Metabolic activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: sister chromatid exchange assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Result: equivocal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**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.

**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

**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

- **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

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.
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

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 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

**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

**SECTION 12: Ecological information**

12.1 Toxicity

**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 Formulation

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):
- 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

M-Factor (Chronic aquatic toxicity):
- 10

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
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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: 0.32 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

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

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

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

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

**Components:**

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

**Sodium hydroxymethanesulphinate:**

12.3 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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- **Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
- **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

14.1 UN number
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according to Regulation (EC) No. 1907/2006

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 11.12.2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>23.03.2020</td>
<td>4164051-00007</td>
<td>Date of first issue: 17.04.2019</td>
</tr>
</tbody>
</table>

| ADN       | UN 3082 |
| ADR       | UN 3082 |
| RID       | UN 3082 |
| IMDG      | UN 3082 |
| IATA      | UN 3082 |

**14.2 UN proper shipping name**

| ADN       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline) |
| ADR       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline) |
| RID       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline) |
| IMDG      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline) |
| IATA      | Environmentally hazardous substance, liquid, n.o.s. (Oxytetracycline) |

**14.3 Transport hazard class(es)**

| ADN       | 9 |
| ADR       | 9 |
| RID       | 9 |
| IMDG      | 9 |
| IATA      | 9 |

**14.4 Packing group**

| ADN       | Packing group: III  
|           | Classification Code: M6  
|           | Hazard Identification Number: 90  
|           | Labels: 9 |
| ADR       | Packing group: III  
|           | Classification Code: M6  
|           | Hazard Identification Number: 90  
|           | Labels: 9  
|           | Tunnel restriction code: (-) |
| RID       | Packing group: III  
|           | Classification Code: M6  
|           | Hazard Identification Number: 90 |
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Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3
REACH - Candidate List of Substances of Very High : Not applicable
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Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
: Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H301 : Toxic if swallowed.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H341 : Suspected of causing genetic defects.
H360D : May damage the unborn child.
H360FD : May damage fertility. May damage the unborn child.
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
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<thead>
<tr>
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</tr>
</tbody>
</table>

#### Acute Tox.
- Acute toxicity

#### Aquatic Acute
- Short-term (acute) aquatic hazard

#### Aquatic Chronic
- Long-term (chronic) aquatic hazard

#### Eye Irrit.
- Eye irritation

#### Muta.
- Germ cell mutagenicity

#### Repr.
- Reproductive toxicity

#### Skin Irrit.
- Skin irritation

#### Skin Sens.
- Skin sensitisation

#### STOT RE
- Specific target organ toxicity - repeated exposure

#### IE OEL
- Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1

#### IE OEL / OELV - 8 hrs (TWA)
- Occupational exposure limit value (8-hour reference period)

#### IE OEL / OELV - 15 min
- Occupational exposure limit value (15-minute reference period)

#### (STEL)

**ADN** - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; **ADR** - European Agreement concerning the International Carriage of Dangerous Goods by Road; **AICS** - Australian Inventory of Chemical Substances; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CLP** - Classification Labelling Packaging Regulation; **EC** - Regulation (EC) No 1272/2008; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DSL** - Domestic Substances List (Canada); **ECHA** - European Chemicals Agency; **EC Number** - European Community number; **ECx** - Concentration associated with x% response; **ELx** - Loading rate associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Office of Chemical Safety and Pollution Prevention; **PBT** - Persistent, Bioaccumulative and Toxic substance; **EPA** - Environmental Protection Agency; **IOELV** - Occupational Exposure Limit Value; **IE OEL** - Ireland. List of Chemical Agents and Occupational Exposure Limit Values; **IE OELV** - Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1; **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; **IDG** - International Maritime Dangerous Goods; **IC50** - Half maximal inhibitory concentration; **IEC** - 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; **NO(A)EC** - No Observed (Adverse) Effect Concentration; **NO(A)EL** - No Observed (Adverse) Effect Level; **NOELR** - No Observable Effect Loading Rate; **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; **RID** - Regulations concerning the International Carriage of Dangerous Goods by Rail; **SADT** - Self-Accelerating Decomposition Temperature; **SDS** - Safety Data Sheet; **SVHC** - Substance of Very High Concern; **TCSI** - Taiwan Chemical Substance Inventory; **TRGS** - Technical Rule for Hazardous Substances; **TSCA** - Toxic Substances Control Act (United States); **UN** - United Nations; **vPvB** - Very Persistent and Very Bioaccumulative

**Further information**

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according to Regulation (EC) No. 1907/2006

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Classification of the mixture:

<table>
<thead>
<tr>
<th></th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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.

IE / EN