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
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone: 353-51-601000
   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: H319: Causes serious eye irritation.
   Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
   Reproductive toxicity, Category 1A: H360FD: May damage fertility. May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Danger
   Hazard statements:
   H317: May cause an allergic skin reaction.
   H319: Causes serious eye irritation.
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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</td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>210-483-1</td>
<td></td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>Skin Sens. 1A; H317 Repr. 1A; H360D</td>
<td></td>
</tr>
<tr>
<td></td>
<td>201-212-8</td>
<td>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td></td>
<td>239-346-4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Oxytetracycline / Diclofenac Formulation

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Revision Date: 10.10.2020  
SDS Number: 4164051-00008  
Date of last issue: 23.03.2020  
Date of first issue: 17.04.2019

| Sodium hydroxymethanesulphinate | 6035-47-8 | Muta. 2; H341  
|                               |           | Repr. 2; H361d | >= 0.1 - < 1 |

For explanation of abbreviations see section 16.

**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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
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.
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 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.

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:
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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>Propylene glycol</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>
<tr>
<td></td>
</tr>
</tbody>
</table>

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</td>
<td>57.8 mg/m3</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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<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 faceshield 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**

Material: Work uniform or laboratory coat.

**Respiratory protection**

Material: 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.
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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
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.

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

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
Method: OECD Test Guideline 474
Result: negative

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.

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 muta-
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 - Assessement : 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

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 through prolonged or repeated exposure.
Oxytetracycline / Diclofenac Formulation

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
## Oxytetracycline / Diclofenac Formulation

| 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, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

### 2-Pyrrolidine:

- **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**  
  - EC50 (Daphnia magna (Water flea)): > 500 mg/l
### Aquatic Invertebrates

**Exposure time:** 48 h

### Toxins to Algae/Aquatic Plants

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Desmodesmus subspicatus (green algae))</th>
<th>Exposure time</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>&gt; 500 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Ecotoxicity:**

**ErC50 (Desmodesmus subspicatus (green algae)):** 22.2 mg/l

**Exposure time:** 72 h

**Toxicity to Microorganisms**

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

### Oxytetracycline

**Toxicity to Fish**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Oryzias latipes (Japanese medaka))</th>
<th>Exposure time</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>110 mg/l</td>
<td>96 h</td>
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</table>

**Toxicity to Daphnia and Other Aquatic Invertebrates**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>621 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>669 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to Algae/Aquatic Plants**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Method</th>
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</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>0.032 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

**NOEC (Anabaena):** 0.0031 mg/l

**Exposure time:** 72 h

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

**Toxicity to Fish**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Test 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>OECD Test Guideline 203</td>
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</table>

**Toxicity to Daphnia and Other Aquatic Invertebrates**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Test Method</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>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

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

**M-Factor (Chronic aquatic toxicity):** 10
**Oxytetracycline / Diclofenac Formulation**

| Aquatic invertebrates | Exposure time: 48 h  
|-----------------------|-----------------------|
| **Toxicity to algae/aquatic plants** | Method: OECD Test Guideline 202  
| 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: 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:** | 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:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 77 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

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

Oxytetracycline / Diclofenac Formulation

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Date of last issue: 23.03.2020
Date of first issue: 17.04.2019

SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.2 UN proper shipping name

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<th>ADN</th>
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<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)</td>
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<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)</td>
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<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (oxytetracycline)</td>
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</table>

14.3 Transport hazard class(es)

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<thead>
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14.4 Packing group

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<tr>
<td>Classification Code</td>
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<td>Labels</td>
<td>9</td>
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</table>

<table>
<thead>
<tr>
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<tr>
<td>Packing group</td>
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<tr>
<td>Hazard Identification Number</td>
<td>90</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
<td>(-)</td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of first issue: 17.04.2019

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 Concern for Authorisation (Article 59):
- Not applicable
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
- 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.
- H360/360D: 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.
Oxytetracycline / Diclofenac Formulation

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**SDS Number:** 4164051-00008  
**Date of last issue:** 23.03.2020  
**Date of first issue:** 17.04.2019

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

**Full text of other abbreviations**

- 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 / OELV - 8 hrs (TWA): Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- IE OEL / OELV - 15 min: Occupational exposure limit value (15-minute reference period)

**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; **AIIC** - Australian Inventory of Industrial Chemicals; **ASTM** - American Society for Testing of Materials; **bw** - Body weight; **CLP** - Classification Labelling Packaging Regulation; **ENCS** - Emergency Schedule; **ECHA** - European Chemicals Agency; **EC** - European Community number; **ECx** - Concentration associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ErCx** - Concentration associated with x% growth rate response; **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; **IECSC** - Inventory of Existing Chemical Substances; **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; **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**

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
Oxytetracycline / Diclofenac Formulation

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Last issue: 17.04.2019


Classification of the mixture:

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

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