1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Oxytetracycline / Diclofenac Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation: Category 2A
Skin sensitisation: Category 1
Reproductive toxicity: Category 1A
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.
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; 25</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</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;= 0.25 -&lt; 1</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>149-44-0</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>
General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

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

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

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

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

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

Notes to physician: Treat symptomatically and supportively.

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
Metal oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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.

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.

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

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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9. PHYSICAL AND CHEMICAL PROPERTIES
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>light brown</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>8.3 - 9.0 (as aqueous solution)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.05 - 1.18 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>47.62 mm²/s</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4,800 mg/kg
LD50 (Mouse): 2,240 mg/kg
Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : 
  LD50 (Rat): 4,840 mg/kg
  Application Route: Intramuscular

  LD50 (Mouse): 3,500 mg/kg
  Application Route: Subcutaneous

Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

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

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

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

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

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

  LD50 (Mouse): 92 - 147 mg/kg
    Application Route: Intravenous

Sodium hydroxymethanesulphinate:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formula-

Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

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

Oxytetracycline:
Remarks : No data available

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

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

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

Sodium hydroxymethanesulphinate:
Species : Rat
Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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

Oxytetracycline:
Remarks : No data available

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

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

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

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

Respiratory or skin 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

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Magnesium oxide:
Test Type: Maximisation Test
Exposure routes: Skin contact
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.1
Revision Date: 2020/03/23
SDS Number: 1313810-00010
Date of last issue: 2019/12/11
Date of first issue: 2017/02/20

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

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.

Benzyl alcohol:
Genotoxicity in vitro:

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo:

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Magnesium oxide:
Genotoxicity in vitro:

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

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

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

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

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

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

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

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

Carcinogenicity:
Not classified based on available information.

Components:

2-Pyrrolidine:
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

Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
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: Test Type: Embryo-foetal development
Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

**Benzyl alcohol:**

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

Effects on 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
### Oxytetracycline / Diclofenac Liquid Formulation

**Application Route:** Ingestion
**Method:** OECD Test Guideline 422
**Result:** negative
**Remarks:** Based on data from similar materials

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

### 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

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Development</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Embryo-foetal toxicity, No teratogenic effects</td>
<td></td>
</tr>
</tbody>
</table>

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

### 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

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Embryo-foetal development</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 414</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

**Reproductive toxicity - Assessment**
- Suspected of damaging the unborn child.

**Effects on foetal development**

**Reproductive toxicity - Assessment**
- Some evidence of adverse effects on development, based on animal experiments.
SAFETY DATA SHEET

**Oxytetracycline / Diclofenac Liquid Formulation**

**Version** 2.1  **Revision Date:** 2020/03/23  **SDS Number:** 1313810-00010  **Date of last issue:** 2019/12/11  **Date of first issue:** 2017/02/20

**STOT - single exposure**  
Not classified based on available information.

**STOT - repeated exposure**  
Not classified based on available information.

**Components:**

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

**Repeated dose toxicity**

**Components:**

**2-Pyrrolidone:**  
Species: Rat  
NOAEL: 207 mg/kg  
Application Route: Ingestion  
Exposure time: 3 Months  
Method: OECD Test Guideline 408

**Oxytetracycline:**  
Species: Rat  
LOAEL: 198 mg/kg  
Application Route: Oral  
Exposure time: 13 Weeks  
Target Organs: Bone  
Remarks: No significant adverse effects were reported

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

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

Species: Rat  
NOAEL: 40 mg/kg  
LOAEL: 100 mg/kg  
Application Route: Intraperitoneal  
Exposure time: 14 Days  
Target Organs: Kidney
Benzyl alcohol:
Species: Rat  
NOAEL: 1.072 mg/l  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 28 Days  
Method: OECD Test Guideline 412

Magnesium oxide:
Species: Rat  
NOAEL: >= 1,000 mg/kg  
Application Route: Ingestion  
Exposure time: 28 Days  
Method: OECD Test Guideline 407  
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat  
LOAEL: 0.25 mg/kg  
Application Route: Oral  
Exposure time: 98 w  
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate  

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: 13 Weeks  
Method: OECD Test Guideline 408

Aspiration toxicity  
Not classified based on available information.
Experience with human exposure

Components:

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Ingestion: Symptoms: Abdominal pain, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

12. ECOLOGICAL INFORMATION

Ecotoxicity

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 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
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Liquid Formulation

Version 2.1 Revision Date: 2020/03/23
SDS Number: 1313810-00010 Date of last issue: 2019/12/11
Date of first issue: 2017/02/20

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

M-Factor (Acute aquatic toxicity): 10

M-Factor (Chronic aquatic toxicity): 10

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

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

Benzyl alcohol:

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

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Magnesium oxide:

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

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

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

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

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

Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 80.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

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

Sodium hydroxymethanesulphinate:

Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h

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

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

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity): NOEC (Danio rerio (zebra fish)): 13.5 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): EC10 (Daphnia magna (Water flea)): 8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: NOEC: 10 mg/l
Exposure time: 4 h

Persistence and degradability

Components:

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

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

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

Bioaccumulative potential

Components:

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

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

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

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

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.
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Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information


Date format : yyyy/mm/dd
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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ID OEL / NAB : Long term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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