SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 4.1 Revision Date: 2020/03/23 SDS Number: 4156030-00007 Date of last issue: 2019/12/11 Date of first issue: 2019/04/17

1. PRODUCT AND COMPANY IDENTIFICATION

   Product name: Oxytetracycline / Diclofenac 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 2B
   Skin sensitisation: Category 1
   Reproductive toxicity: Category 1A
   Specific target organ toxicity - repeated exposure: Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
   Short-term (acute) aquatic hazard: Category 1
   Long-term (chronic) aquatic hazard: Category 1

   GHS label elements
   Hazard pictograms: 
   Signal word: Danger
   Hazard statements: H317 May cause an allergic skin reaction.
                       H320 Causes eye irritation.
                       H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 -&lt; 25</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 -&lt; 2.5</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

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

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

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

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction. Causes eye irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

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

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Sodium oxides
Metal oxides

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

Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

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.

Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling
- Do not get on skin or clothing.
- Do not breathe 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
### 8. EXPOSURE CONTROLS/PERSOAL PROTECTION

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin sensitisation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>NAB (Fumes)</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**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**

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

**Filter type**: Combined particulates and organic vapour type

**Hand protection Material**: Chemical-resistant gloves

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat.

**Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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
9. 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

Flammability (liquids): No data available

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.

Molecular weight : No data available

Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Inhalation</th>
<th>Skin contact</th>
<th>Ingestion</th>
<th>Eye contact</th>
</tr>
</thead>
</table>

**Acute toxicity**
Not classified based on available information.

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

**Components:**

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

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

**Oxytetracycline:**
- **Acute oral toxicity**
  - LD50 (Rat): 4,800 mg/kg

  - LD50 (Mouse): 2,240 mg/kg

  - Remarks: Evidence of phototoxicity was observed

- **Acute inhalation toxicity**
  - Remarks: No data available
Acute dermal toxicity : Remarks: No data available
Acute toxicity (other routes of administration)
LD50 (Rat): 4,840 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 3,500 mg/kg
Application Route: Subcutaneous

Magnesium oxide:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute inhalation toxicity : LC50 (Rat): > 2.1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Sodium [2-[2,6-dichlorophenyl]amino]phenyl]acetate:
Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg
Acute toxicity (other routes of administration)
LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous
LD50 (Mouse): 92 - 147 mg/kg
Application Route: Intravenous

Sodium hydroxymethanesulphinate:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

2-Pyrrolidone:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Oxytetracycline:  
Remarks: No data available

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
Remarks: Based on data from similar materials

Serious eye damage/eye irritation  
Causes eye irritation.

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

Oxytetracycline:  
Remarks: No data available

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

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

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

Respiratory or skin sensitisation  
Skin sensitisation  
May cause an allergic skin reaction.
Respiratory sensitisation
Not classified based on available information.

Components:

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

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

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
  - Remarks: Based on data from similar materials
  - Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative

- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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<td>2020/03/23</td>
<td>4156030-00007</td>
<td>2019/12/11</td>
<td>2019/04/17</td>
</tr>
</tbody>
</table>

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.

### 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:
Species: CHO
Result: negative

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

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

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

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

**Components:**

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

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

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

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen.
Magnesium oxide:
Species: Mouse
Application Route: Ingestion
Exposure time: 96 weeks
Result: negative
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

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

Oxytetracyline:
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
### Reproductive toxicity - Assessment

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>NOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>1,200 mg/kg body weight</td>
<td>1,500 mg/kg body weight</td>
<td>No teratogenic effects</td>
<td>Maternal toxicity observed.</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>1,325 mg/kg body weight</td>
<td>2,100 mg/kg body weight</td>
<td>No teratogenic effects</td>
<td>Maternal toxicity observed.</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>41.5 mg/kg body weight</td>
<td></td>
<td>Postimplantation loss., No foetal abnormalities</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>Intramuscular</td>
<td>20.75 mg/kg body weight</td>
<td></td>
<td>Skeletal and visceral variations, Postimplantation loss.</td>
<td></td>
</tr>
</tbody>
</table>

### Magnesium oxide:

**Effects on fertility**

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

**Effects on foetal development**

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

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

**Effects on fertility**

- Test Type: Fertility
- Species: Rat, male and female
- Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility

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

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

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

Sodium hydroxymethanesulphinate:

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

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 414
  - Result: positive
  - Remarks: Based on data from similar materials

Reproductive toxicity - Assessment:
Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:

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

**Components:**

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

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

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

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

Species: Rat  
NOAEL: 40 mg/kg  
LOAEL: 100 mg/kg  
Application Route: Intraperitoneal  
Exposure time: 14 Days  
Target Organs: Kidney

**Magnesium oxide:**
Species: Rat  
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
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<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<td>4.1</td>
<td>2020/03/23</td>
<td>4156030-00007</td>
<td>2019/12/11</td>
<td>2019/04/17</td>
</tr>
</tbody>
</table>

- **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

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**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

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### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components**:

**2-Pyrolidone**:
- **Toxicity to fish**: EC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
  - **Exposure time**: 96 h
  - **Method**: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 500 mg/l
  - **Exposure time**: 48 h
Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l Exposure time: 72 h

Toxicity to microorganisms: EC50: > 1,000 mg/l Exposure time: 30 min
Method: OECD Test Guideline 209

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

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 621 mg/l Exposure time: 48 h
Method: OECD Test Guideline 202

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

Toxicity to algae/aquatic plants: EC50 (Anabaena): 0.032 mg/l Exposure time: 72 h

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

M-Factor (Acute aquatic toxicity): 10

M-Factor (Chronic aquatic toxicity): 10

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

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

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

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Remarks: Based on data from similar materials
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
<td>EC50: &gt; 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
<td>EC50 (Daphnia magna (Water flea)): 80.1 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
<td>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</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate:</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 10,000 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
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<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials</td>
<td></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
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</tbody>
</table>
## Toxicity to fish (Chronic toxicity)
- **NOEC (Danio rerio (zebra fish)):** 13.5 mg/l
- **Exposure time:** 35 d
- **Method:** OECD Test Guideline 210
- **Remarks:** Based on data from similar materials

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

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

### Persistence and degradability

#### Components:

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

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

### Bioaccumulative potential

#### Components:

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

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

### Mobility in soil
- No data available

### Other adverse effects
- No data available

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods
- **Waste from residues:** Dispose of in accordance with local regulations.
- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal.
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.

**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

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 Organization 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 - Transport 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.