1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sulfadoxine / Trimethoprim 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 1
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 2 (Bone marrow)
Long-term (chronic) aquatic hazard: Category 3

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
**SAFETY DATA SHEET**

**Sulfadoxine / Trimethoprim Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.6</td>
<td>2020/03/23</td>
<td>1681361-00009</td>
<td>2019/09/13</td>
<td>2017/05/17</td>
</tr>
</tbody>
</table>

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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td></td>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>5464-28-8</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td></td>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 2 - &lt; 3</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 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 immediately. |
| 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 |
| Causes serious eye damage. Suspected of damaging 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
  - Metal oxides
- **Specific extinguishing methods**: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
- **Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 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.
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

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: Use only with adequate ventilation.
Advice on safe handling: Avoid inhalation of vapour or mist.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
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/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>KTD</td>
<td>2 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of
the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**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: Particulates type

**Hand protection**
- Chemical-resistant gloves

**Remarks**
- Consider double gloving.

**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.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>liquid</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>light brown, yellow</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>9.3 - 10.0</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 : No data available
Density : 1.210 - 1.250 g/cm³
Solubility(ies) 
   Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity 
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : Not applicable
Particle size : Not applicable

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
   Acids
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

**Components:**

1,3-Dioxan-5-ol:
- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
- **Acute dermal toxicity:** LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
- **Acute dermal toxicity:** LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Sulfadoxine:
- **Acute oral toxicity:** LD50 (Mouse): 5,200 mg/kg

Trimethoprim:
- **Acute oral toxicity:** LD50 (Rat): 1,500 - 5,300 mg/kg
  LD50 (Mouse): 1,910 - 7,000 mg/kg
- **Acute toxicity (other routes of administration):** LD50 (Rat): 400 - 500 mg/kg
  Application Route: Intraperitoneal
  LD50 (Dog): 90 mg/kg
  Application Route: Intravenous
  LD50 (Mouse): 132 mg/kg
  Application Route: Intravenous

Sodium hydroxide:
- **Acute inhalation toxicity:** Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation:
Not classified based on available information.
**Product:**
Result: No skin irritation

**Components:**

**1,3-Dioxan-5-ol:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

**1,3-Dioxolan-4-ylmethanol:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

**Sulfadoxine:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: Irritating

**Sodium hydroxide:**
Result: Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**

**1,3-Dioxan-5-ol:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

**1,3-Dioxolan-4-ylmethanol:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

**Sulfadoxine:**
Result: Irritating

**Sodium hydroxide:**
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol:</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol:</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>trimethoprim:</td>
<td>Maximisation Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td></td>
<td>Not a skin sensitizer.</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide:</td>
<td>Human repeat insult patch test (HRIPT)</td>
<td>Skin contact</td>
<td></td>
<td>negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
Remarks: Based on data from similar materials

### 1,3-Dioxolan-4-ylmethanol:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Result: negative

### trimethoprim:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

- Test Type: Chromosomal aberration
  Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: negative

**Genotoxicity in vivo**
- Test Type: Micronucleus test
  Species: Rat
  Result: negative

- Test Type: Chromosomal aberration
  Species: Humans
  Result: negative

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging the unborn child.

**Components:**

### trimethoprim:

**Effects on fertility**
- Test Type: Fertility
  Species: Rat
  Application Route: Oral
  Fertility: NOAEL: 70 mg/kg body weight
  Result: No effects on fertility

**Effects on foetal development**
- Test Type: Development
  Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Effects on newborn
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Embryotoxic effects.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 15 mg/kg body weight
Result: Embryotoxic effects., Teratogenic effects

Test Type: Development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 1.7 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

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

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

**Components:**

**Sulfadoxine:**
Assessment : May cause respiratory irritation.

**STOT - repeated exposure**
May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

**Components:**

**trimethoprim:**
Target Organs : Bone marrow
Assessment : Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:
trimethoprim:
Species : Rat
NOAEL : 100 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Bone marrow, Liver, Pituitary gland, Thyroid

Species : Rat
NOAEL : 300 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Bone marrow

Species : Dog
NOAEL : 2.5 mg/kg
LOAEL : 45 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Thyroid

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Sulfadoxine:
Ingestion : Target Organs: Blood
Symptoms: The most common side effects are: Nausea, Vomiting, Headache, anemia, Rash, Stevens-Johnson syndrome

trimethoprim:
Ingestion : Target Organs: Bone marrow
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
1,3-Dioxan-5-ol:
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 : EL50 (Daphnia magna (Water flea)): > 100 mg/l
### aquatic invertebrates

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>algae/aquatic plants</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>algae/aquatic plants</td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxins

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>algae/aquatic plants</td>
<td>EC50 (Anabaena flos-aquae (cyanobacterium))</td>
<td>17 mg/l</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 1,3-Dioxolan-4-ylmethanol

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>LL50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>fish</td>
<td></td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>microorganisms</td>
<td>EC10</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

### Sulfadoxine

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>LC50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>fish</td>
<td></td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Effect</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>microorganisms</td>
<td>EC50</td>
<td>(Anabaena flos-aquae (cyanobacterium))</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
NOEC (Anabaena flos-aquae (cyanobacterium)): 3.9 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

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

NOEC (Daphnia magna (Water flea)): 6.2 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

trimethoprim:

Toxicity to fish:

LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Daphnia magna Straus): 92 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:

EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l
Exposure time: 72 h

EC50 (Anabaena flos-aquae): 253 mg/l
Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity):

NOEC (Zebrafish): 0.157 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates:

NOEC (Daphnia magna (Water flea)): 6 mg/l
aquatic invertebrates (Chronic toxicity)  
Exposure time: 21 d

Persistence and degradability

Components:

1,3-Dioxan-5-ol:
Biodegradability  :  Result: Inherently biodegradable.  
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Biodegradability  :  Result: Inherently biodegradable.  
Remarks: Based on data from similar materials

Sulfadoxine:
Biodegradability  :  Result: Not readily biodegradable.  
Biodegradation: 5 %  
Exposure time: 28 d  
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:
Partition coefficient: n-octanol/water  :  log Pow: -0.65

trimethoprim:
Partition coefficient: n-octanol/water  :  log Pow: 0.91

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.  
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

Version 2.6  Revision Date: 2020/03/23  SDS Number: 1681361-00009  Date of last issue: 2019/09/13  Date of first issue: 2017/05/17

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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 : Sodium hydroxide
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
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

Version 2.6
Revision Date: 2020/03/23
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Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / C: Ceiling limit
ID OEL / KTD: Ceiling

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 - Toxics 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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