## SECTION 1. IDENTIFICATION

Product name: Sulfadoxine / Trimethoprim Formulation

**Manufacturer or supplier’s details**

- **Company**: MSD
- **Address**: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
- **Telephone**: 908-740-4000
- **Emergency telephone**: 1-908-423-6000
- **E-mail address**: EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

- **Recommended use**: Veterinary product

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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

- **Serious eye damage**: Category 1
- **Reproductive toxicity**: Category 2
- **Specific target organ toxicity - repeated exposure**: Category 2 (Bone marrow)
- **Short-term (acute) aquatic hazard**: Category 3
- **Long-term (chronic) aquatic hazard**: Category 3

### GHS label elements

- **Hazard pictograms**: ![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:
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 vapors.
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>5464-28-8</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 -&lt; 5</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 2 -&lt; 3</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 : Do not breathe mist or vapors.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage : Keep in properly labeled 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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>400 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>CMP-C</td>
<td>2 mg/m³</td>
<td>AR 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., 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. 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

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

**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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>liquid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>light brown, yellow</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>9,3 - 10,0</td>
</tr>
</tbody>
</table>
### Melting point/freezing point
Not applicable

### Initial boiling point and boiling range
No data available

### 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

### Vapor pressure
No data available

### Relative vapor 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

### Autoignition 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

### SECTION 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.

SECTION 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: > 5.000 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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Trimethoprim:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
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  
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:  
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vitro : 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 fetal 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
  - **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

### SECTION 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadoxine</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to microorganisms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>EC10: &gt; 1.000 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to fish</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadoxine</td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
<td>Based on data from similar materials</td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td>Remarks: Based on data from similar materials</td>
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</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadoxine</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Anabaena flos-aquae (cyanobacterium)): &gt; 17 mg/l</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>
### Remarks:
Based on data from similar materials

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):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea)):</td>
<td>6,2 mg/l</td>
<td>21 d</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50:</td>
<td>&gt; 1.000 mg/l</td>
<td>3 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Remarks:
Based on data from similar materials

NOEC: 1.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

Trimethoprim:

Toxicity to fish:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>LC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow)):</td>
<td>100 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (microalgae)):</td>
<td>80,3 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)):</td>
<td>16 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

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):

<table>
<thead>
<tr>
<th>Test Type</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Zebrafish):</td>
<td>0,157 mg/l</td>
<td>21 d</td>
</tr>
</tbody>
</table>
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 6 mg/l
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

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
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.

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits
ACGIH / C : Ceiling limit
AR OEL / CMP-C : Ceiling value

AIIIC - Australian Inventory of Industrial Chemicals; 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
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
--- | --- | --- | --- | ---
3.7 | 27.08.2021 | 1686799-00013 | 03.03.2021 | 17.05.2017

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; TECI - Thailand Existing Chemicals Inventory; 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.