SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier’s details

Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

Hazard pictograms : [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.
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.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>Flammable liquids, Category 4, Eye irritation, Category 2A</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>5464-28-8</td>
<td>Eye irritation, Category 2A</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>Skin irritation, Category 2, Eye irritation, Category 2A, Specific target organ toxicity - single exposure, Category 3, Short-term (acute) aquatic hazard, Category 2, Long-term (chronic) aquatic hazard, Category 2</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>Acute toxicity (Oral), Category 4, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Bone marrow), Category 1</td>
<td>&gt;= 3 &lt; 5</td>
</tr>
</tbody>
</table>
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Sulfadoxine / Trimethoprim Formulation

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Date of first issue: 17.05.2017

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazard Class</th>
<th>Date of Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>Corrosive to Metals, Category 1</td>
<td>&gt;= 2 - &lt; 3</td>
</tr>
<tr>
<td></td>
<td>Skin corrosion, Category 1A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serious eye damage, Category 1</td>
<td></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 spillages 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.

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.

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>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: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: light brown, yellow
Odor: No data available
Odor Threshold: No data available
pH: 9.3 - 10.0
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) : No data available
  Water solubility
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
  Viscosity, kinematic
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
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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
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.
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<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>4.4</td>
<td>27.08.2021</td>
<td>1681353-00013</td>
<td>03.03.2021</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

- **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  

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

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials  
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials  

Toxicity to microorganisms : EC10: > 1.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials  

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

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

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

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

### Sulfadoxine:

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

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NOEC (Anabaena flos-aquae (cyanobacterium)): 3,9 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 6,2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
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 (Water flea)): 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 (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
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

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.

Domestic regulation

ANTT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

Version 4.4	Revision Date: 27.08.2021	SDS Number: 1681353-00013	Date of last issue: 03.03.2021
Date of first issue: 17.05.2017

(LINACH)

Brazil. List of chemicals controlled by the Federal Police: Sodium hydroxide

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)
- ACGIH / C: Ceiling limit

All abbreviations: AIIC - 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 - 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 Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LDS0 - 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 Sub-
stances 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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