SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier's details

Company : MSD
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park
New South Wales, 2113 Australia
Telephone : (61)-02-8988-8000
Emergency telephone number : (61)-02-8988-8000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 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)

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.

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.
P280 Wear eye protection/face protection.
P281 Use personal protective equipment as required.

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 or doctor/physician.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>1,3-Dioxan-5-ol</td>
</tr>
<tr>
<td></td>
<td>1,3-Dioxolan-4-ylmethanol</td>
</tr>
<tr>
<td></td>
<td>Sulfadoxine</td>
</tr>
<tr>
<td></td>
<td>trimethoprim</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</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. 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.

SECTION 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.
**SECTION 7. HANDLING AND STORAGE**

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>See Engineering measures under EXPOSURE CONTROLS/PERSOANL PROTECTION section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>Use only with adequate ventilation.</td>
</tr>
</tbody>
</table>
| 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. |
| 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 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 |

**SECTION 8. EXPOSURE CONTROLS/PERSOANL PROTECTION**

<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>Peak limit</td>
<td>2 mg/m³</td>
<td>AU 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
- **Material**: 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: liquid
- **Colour**: light brown, yellow
- **Odour**: No data available
- **Odour 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

### Vapour pressure
- No data available

### Relative vapour density
- No data available

### Relative density
- No data available

### Density
- 1.201 - 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

## 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

### Exposure routes
- Inhalation
- Skin contact
- Ingestion
- Eye contact
Acute toxicity
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>Acute toxicity estimate: &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method:</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

1,3-Dioxan-5-ol:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

1,3-Dioxolan-4-ylmethanol:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Sulfadoxine:

| Acute oral toxicity | LD50 (Mouse): 5,200 mg/kg |

trimethoprim:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 1,500 - 5,300 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Mouse): 1,910 - 7,000 mg/kg</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 400 - 500 mg/kg</td>
</tr>
<tr>
<td>Application Route: Intrapерitoneal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): 90 mg/kg</td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 132 mg/kg</td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
</tbody>
</table>

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:
- **Sulfadoxine**: Rabbit
- **1,3-Dioxolan-4-ylmethanol**: Rabbit
- **Sodium hydroxide**: Rabbit

### Method:
- **Sulfadoxine**: OECD Test Guideline 404
- **1,3-Dioxolan-4-ylmethanol**: OECD Test Guideline 404
- **Sodium hydroxide**: OECD Test Guideline 405

### Result:
- **Sulfadoxine**: Irritating
- **1,3-Dioxolan-4-ylmethanol**: Irritation to eyes, reversing within 21 days
- **Sodium hydroxide**: Corrosive after 3 minutes or less of exposure
- **Sodium hydroxide**: Irreversible effects on the eye

### Remarks:
- Based on data from similar materials

### 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:

1,3-Dioxan-5-ol:
- 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

1,3-Dioxolan-4-ylmethanol:
- 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

Trimethoprim:
- Test Type: Maximisation Test
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Not a skin sensitizer.

Sodium hydroxide:
- Test Type: Human repeat insult patch test (HRIPT)
- Exposure routes: Skin contact
- Result: negative

Chronic toxicity

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 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:
Species: Rat
Test Type: Micronucleus test
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
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
| **Toxicity to microorganisms** | EC10: > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1,3-Dioxolan-4-ylmethanol:</strong></td>
<td></td>
</tr>
</tbody>
</table>
**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 |
| **Sulfadoxine:** |  
**Toxicity to fish**  
LC50 (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** | EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials |
| **Toxicity to algae/aquatic plants** | EC50 (Anabaena flos-aquae (cyanobacterium)): 17 mg/l  
Exposure time: 72 h  
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 |
## Sulfadoxine / Trimethoprim Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates ( Chronic toxicity)</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to fish</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Persistence and degradability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l</td>
<td>EC50: &gt; 1,000 mg/l</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 100 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 3 h</td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 6.2 mg/l</td>
<td>NOEC: 1,000 mg/l</td>
<td>NOEC (Zebrafish): 0.157 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Exposure time: 3 h</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC: 6.2 mg/l</td>
<td>NOEC (Daphnia magna Straus): 92 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Anabaena flos-aquae): 253 mg/l</td>
<td>EC50 (Anabaena flos-aquae): 26 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC10 (Anabaena flos-aquae): 26 mg/l</td>
<td>NOEC (Daphnia magna (Water flea)): 6 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 21 d</td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Components:**

- **1,3-Dioxan-5-ol:**
  - Biodegradability: Result: Inherently biodegradable.
  - Remarks: Based on data from similar materials
**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>2.5</td>
<td>09/13/2019</td>
<td>1681355-00008</td>
<td>24.04.2019</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

### 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.

#### National Regulations

**ADG**
SAFETY DATA SHEET

Sulfadoxine / Trimethoprim Formulation

Version 2.5  Revision Date: 09/13/2019  SDS Number: 1681355-00008  Date of last issue: 24.04.2019
Date of first issue: 17.05.2017

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

- AICS : not determined
- DSL : not determined
- IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Revision Date : 09/13/2019

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / C : Ceiling limit
AU OEL / Peak limit : Exposure standard - peak

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 Or-
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.

AU / EN