SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Sulfadoxine / Trimethoprim Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Serious eye damage, Category 1
   H318: Causes serious eye damage.
   Reproductive toxicity, Category 2
   H361d: Suspected of damaging the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2
   H373: May cause damage to organs through prolonged or repeated exposure.
   Long-term (chronic) aquatic hazard, Category 3
   H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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 through prolonged or repeated exposure.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

Version 3.3  Revision Date: 23.03.2020  SDS Number: 1686809-00009  Date of last issue: 13.09.2019  Date of first issue: 17.05.2017

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.

Hazardous components which must be listed on the label:
trimethoprim
Sodium hydroxide

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</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>225-248-9</td>
<td></td>
<td>1-3-Dioxan-5-ol</td>
<td>Eye Irrit.2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>5464-28-8</td>
<td>226-758-4</td>
<td></td>
<td>1-3-Dioxolan-4-ylmethanol</td>
<td>Eye Irrit.2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>219-504-9</td>
<td></td>
<td>Sulfadoxine</td>
<td>Skin Irrit.2; H315 Eye Irrit.2; H319 STOT SE3; H335 Aquatic Chronic2; H411</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>212-006-2</td>
<td></td>
<td>trimethoprim</td>
<td>Acute Tox.4; H302 Repr.2; H361d STOT RE1; H372 Aquatic Chronic2; H411</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>011-002-00-6</td>
<td>Sodium hydroxide</td>
<td>Met. Corr.1; H290 Skin Corr.1A; H314 Eye Dam.1; H318</td>
<td>&gt;= 2 - &lt; 3</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

Version: 3.3  Revision Date: 23.03.2020  SDS Number: 1686809-00009  Date of last issue: 13.09.2019

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides, Metal oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1686809-00009
Date of last issue: 13.09.2019
Date of first issue: 17.05.2017

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>


Sulfadoxine / Trimethoprim Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1686809-00009
Date of last issue: 13.09.2019
Date of first issue: 17.05.2017

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadoxine</td>
<td></td>
<td>TWA</td>
<td>Internal</td>
<td>40 µg/m³ (OEB 3)</td>
</tr>
<tr>
<td>trimethoprim</td>
<td></td>
<td>Wipe limit</td>
<td>Internal</td>
<td>400 µg/100 cm²</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td></td>
<td>TWA</td>
<td>Internal</td>
<td>0.2 mg/m³ (OEB 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>

Further information: Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.

8.2 Exposure controls

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

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.

Hand protection

Material : Chemical-resistant gloves
Remarks : Consider double gloving.
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.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 143

Filter type : Particulates type (P)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>light brown, yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>9.3 - 10.0</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1,210 - 1,250 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Molecular weight : Not applicable
Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents
                    Acids

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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:
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1686809-00009
Date of last issue: 13.09.2019
Date of first issue: 17.05.2017

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
Sulfadoxine / Trimethoprim Formulation

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
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days
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
**Sulfadoxine / Trimethoprim Formulation**

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 406</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**trimethoprim:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Sodium hydroxide:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**1,3-Dioxan-5-ol:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative</th>
</tr>
</thead>
</table>

**trimethoprim:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration Result: negative</td>
</tr>
</tbody>
</table>

---

**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006
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: 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 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  
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**

12.1 Toxicity

**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
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

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to microorganisms:

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
**Sulfadoxine / Trimethoprim Formulation**

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- NOEC: 6,2 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- 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: 0,157 mg/l
  - Exposure time: 21 d
  - Species: Zebrafish
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
  - NOEC: 6 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)

### 12.2 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

12.3 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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good
14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
**SAFETY DATA SHEET**
**according to Regulation (EC) No. 1907/2006**

**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>3.3</td>
<td>23.03.2020</td>
<td>1686809-00009</td>
<td>13.09.2019</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

**Full text of H-Statements**

H290 : May be corrosive to metals.
H302 : Harmful if swallowed.
H314 : Causes severe skin burns and eye damage.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H335 : May cause respiratory irritation.
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Met. Corr. : Corrosive to metals
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
FOR-2011-12-06-1358 / T : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 : Ceiling

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC Number - European Community number; 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; 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 Organisa-tion for Standardization; KECl - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature;
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadoxine / Trimethoprim Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1686809-00009
Date of last issue: 13.09.2019
Date of first issue: 17.05.2017

SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Eye Dam. 1</th>
<th>Repr. 2</th>
<th>STOT RE 2</th>
<th>Aquatic Chronic 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H318</td>
<td>H361d</td>
<td>H373</td>
<td>H412</td>
</tr>
</tbody>
</table>

Classification procedure:
- Calculation method

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.

NO / EN