SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sulfamethoxazole / Trimethoprim Injection Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 5
Skin corrosion/irritation: Sub-category 1B
Serious eye damage/eye irritation: Category 1
Reproductive toxicity: Category 2
Specific target organ toxicity - single exposure: Category 3
Specific target organ toxicity - repeated exposure: Category 2 (Bone marrow)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger

Hazard statements:
H303 May be harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P361 + P354 + P316 IF ON SKIN: Take off immediately all contaminated clothing. Immediately rinse with water for several minutes. Get emergency medical help immediately.
P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately.
P305 + P354 + P338 + 316 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get emergency medical help immediately.
P318 IF exposed or concerned, get medical advice.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection
Formulation

Version 2.1
Revision Date: 27.08.2021
SDS Number: 7848287-00003
Date of last issue: 09.04.2021
Date of first issue: 03.03.2021

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention immediately.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention immediately.
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.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : May be harmful if swallowed.
Causes serious eye damage.
May cause respiratory irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Causes severe burns.
Causes digestive tract burns.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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Dry chemical media: None known.

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Nitrogen oxides (NOx)
- Sulphur oxides
- Carbon oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
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.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
  - Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>TWA</td>
<td>3 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>6 ppm</td>
<td>ACGIH</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>
</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.
- Laboratory operations do not require special containment.

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:
- Combined particulates and organic vapour type

Hand protection:
- Material: Chemical-resistant gloves
Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a 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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: light yellow

Odour: No data available

Odour Threshold: No data available

pH: 9.5 - 10.5

Melting point/freezing point: No data available

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: 1.050 - 1.230 g/cm³
Solubility(ies): No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity: No data available
Viscosity, kinematic: Not data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents, Acids
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 4,368 mg/kg
Method: Calculation method
Acute inhalation toxicity: Acute toxicity estimate: > 40 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

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

Sulfamethoxazole:
Acute oral toxicity : LD50 (Mouse): 2,300 mg/kg

Ethanolamine:
Acute oral toxicity : LD50 (Rat): 1,089 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
Acute dermal toxicity : LD50 (Rabbit, female): 1,018 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

Skin corrosion/irritation
Causes severe burns.

Components:

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

Sulfamethoxazole:
Species : Rabbit
Result : No skin irritation

Ethanolamine:
Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour 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

Ethanolamine:
Species : Rabbit
Result : Irreversible effects on the eye

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

Sulfamethoxazole:
Test Type : Magnusson-Kligman-Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Ethanolamine:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Result: negative
Remarks: Based on data from similar materials

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

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro
Result: negative

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
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Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
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.

Components:

Sulfamethoxazole:
Species: Mouse
Application Route: Ingestion
Exposure time: 26 weeks
Result: negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Ethanolamine:
Effects on fertility:
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
**Effects on foetal development**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>

**Remarks:** Based on data from similar materials.

**Trimethoprim:**

**Effects on fertility**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Fertility</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 70 mg/kg body weight</td>
<td>No effects on fertility</td>
</tr>
</tbody>
</table>

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 70 mg/kg body weight</td>
<td>Effects on newborn</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

**Remarks:** Maternal toxicity observed.

**Effects on development**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 70 mg/kg body weight</td>
<td>Embryotoxic effects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

**Remarks:** Maternal toxicity observed.

**Developmental Toxicity**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 15 mg/kg body weight</td>
<td>Embryotoxic effects., Teratogenic effects</td>
</tr>
</tbody>
</table>

**Remarks:** Maternal toxicity observed.

**Developmental Toxicity**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Hamster</td>
<td>Oral</td>
<td>LOAEL: 1.7 mg/kg body weight</td>
<td>Embryotoxic effects., No teratogenic effects</td>
</tr>
</tbody>
</table>

**Remarks:** Maternal toxicity observed.

**Developmental Toxicity**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>LOAEL: 100 mg/kg body weight</td>
<td>Embryotoxic effects., No teratogenic effects</td>
</tr>
</tbody>
</table>

**Remarks:** Maternal toxicity observed.

**Reproductive toxicity - Assessment**

Suspected of damaging the unborn child.

**STOT - single exposure**

May cause respiratory irritation.
Components:

Ethanolamine:
Assessment: May cause respiratory irritation.

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

Components:

Ethanolamine:
Assessment: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Trimethoprim:
Target Organs: Bone marrow
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ethanolamine:
Species: Rat
NOAEL: > 120 mg/kg
Application Route: Ingestion
Exposure time: > 75 Days
Remarks: Based on data from similar materials

Species: Rat
NOAEL: >= 0.15 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

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
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### Sulfamethoxazole / Trimethoprim Injection

**Formulation**

**Version** 2.1  
**Revision Date:** 27.08.2021  
**SDS Number:** 7848287-00003  
**Date of last issue:** 09.04.2021  
**Date of first issue:** 03.03.2021

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2.5 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>45 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Thyroid</td>
<td></td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Trimethoprim:**

**Ingestion:**

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

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

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

**Toxicity to fish:**

- LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
  Exposure time: 96 h  
  Remarks: Based on data from similar materials

**Toxicity to daphnia and other 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

**Sulfamethoxazole:**

**Toxicity to fish:**

- LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l  
  Exposure time: 96 h

**Toxicity to daphnia and other:**

- EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l
aquatic invertebrates: Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0268 mg/l
Exposure time: 96 h

NOEC (Synechococcus leopoliensis (blue-green algae)): 0.0059 mg/l
Exposure time: 96 h

M-Factor (Acute aquatic toxicity): 10

Toxicity to microorganisms: NOEC (activated sludge): 3.76 mg/l
Method: OECD Test Guideline 301D

Toxicity to fish (Chronic toxicity):
NOEC: 0.533 mg/l
Exposure time: 21 d
Species: Danio rerio (zebra fish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 0.01 mg/l
Exposure time: 30 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity): 10

Ethanolamine:
Toxicity to fish:
LC50 (Cyprinus carpio (Carp)): 349 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 65 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms:
EC10 (Pseudomonas putida): > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):
NOEC: 1.24 mg/l
Exposure time: 41 d
Species: Oryzias latipes (Orange-red killifish)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
  NOEC: 0.85 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)

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)

Persistence and degradability

Components:

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

Sulfamethoxazole:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Ethanolamine:
Biodegradability: Result: Readily biodegradable.
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Biodegradation: > 90 %
Exposure time: 21 d
Method: OECD Test Guideline 301A

Bioaccumulative potential

Components:

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

Sulfamethoxazole:
Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): < 120
Partition coefficient: n-octanol/water : log Pow: 0.89

Ethanolamine:
Partition coefficient: n-octanol/water : log Pow: -2.3
Method: OECD Test Guideline 107

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 2491
Proper shipping name : ETHANOLAMINE SOLUTION
Class : 8
Packing group : III
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Sulfamethoxazole / Trimethoprim Injection
Formulation

Version: 2.1
Revision Date: 27.08.2021
SDS Number: 7848287-00003
Date of last issue: 09.04.2021
Date of first issue: 03.03.2021

Labels:
IATA-DGR
UN/ID No.: UN 2491
Proper shipping name: Ethanolamine solution
Class: 8
Packing group: III
Labels: Corrosive
Packing instruction (cargo aircraft): 856
Packing instruction (passenger aircraft): 852

IMDG-Code
UN number: UN 2491
Proper shipping name: ETHANOLAMINE SOLUTION (Sulfamethoxazole)
Class: 8
Packing group: III
Labels: 8
EmS Code: F-A, S-B
Marine pollutant: yes

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

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

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection
Formulation

Version 2.1  Revision Date: 27.08.2021  SDS Number: 7848287-00003  Date of last issue: 09.04.2021

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit

All abbreviations defined in the text.

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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