SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection Formulation

Version: 2.1  Revision Date: 2021/08/27  SDS Number: 7848288-00003  Date of last issue: 2021/04/09
Date of first issue: 2021/03/03

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Sulfamethoxazole / Trimethoprim Injection Formulation

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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: 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:
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.
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:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.
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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 70 - &lt; 80</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Conc. Range</th>
</tr>
</thead>
<tbody>
<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>7.619</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 10</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 : 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)
Dry chemical

Unsuitable extinguishing 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

   Handling
   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.

**Avoidance of contact**
- Oxidizing agents
- Acids

**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.

**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:
  - Strong oxidizing agents

**Packaging material**
- Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Threshold limit value and permissible exposure limits for each component in the work environment**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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>OEL-M</td>
<td>3 ppm 7.5 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></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., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
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**

**Hand protection Material**: Combined particulates and organic vapour type

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Physical state**: liquid

**Colour**: light yellow

**Odour**: No data available

**Odour Threshold**: No data available

**Melting point/freezing point**: No data available

**Boiling point, initial boiling point and boiling range**: No data available

**Flammability (solid, gas)**: Not applicable

**Flammability (liquids)**: No data available

**Lower explosion limit and upper explosion limit / flammability limit**

**Upper explosion limit / Upper flammability limit**: No data available

**Lower explosion limit / Lower flammability limit**: No data available

**Flash point**: No data available

**Decomposition temperature**: No data available

**pH**: 9.5 - 10.5
Evaporation rate : No data available
Auto-ignition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Density and / or relative density
  Relative density : No data available
  Density : 1.050 - 1.230 g/cm³
Relative vapour density : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle characteristics
  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
Not classified based on available information.

**Product:**

**Acute oral toxicity**
- Acute toxicity estimate: > 2,000 mg/kg
- Method: Calculation method

**Acute inhalation toxicity**
- Acute toxicity estimate: > 20 mg/l
- Exposure time: 4 h
- Test atmosphere: vapour
- Method: Calculation method

**Acute dermal 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

**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
- **Result**: Irritation to eyes, reversing within 21 days
- **Method**: OECD Test Guideline 405
- **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
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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
- 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

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

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Humans
  Result: negative
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<tr>
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</tr>
</tbody>
</table>

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

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**
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
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:

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 aquatic invertebrates:** EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l
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 fish (Chronic toxicity):** NOEC (Danio rerio (zebra fish)): 0.533 mg/l
Exposure time: 21 d

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

**M-Factor (Chronic aquatic toxicity):** 10

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

**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 fish (Chronic toxicity):

- NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l
  Exposure time: 41 d
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 0.85 mg/l
  Exposure time: 21 d

Toxicity to microorganisms:

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

**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 (Zebrafish): 0.157 mg/l
  Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 6 mg/l
  Exposure time: 21 d

**Persistence and degradability**

**Components:**

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

Biodegradability: Result: Inherently biodegradable.
Remarks: Based on data from similar materials

**Sulfamethoxazole:**

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

Hazardous to the ozone layer
Not applicable

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
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection
Formulation

Class: 8
Packing group: III
Labels: 8

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: Corrosive
EmS Code: F-A, S-B
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Aminoethanol</td>
<td>107</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable
**SAFETY DATA SHEET**

**Sulfamethoxazole / Trimethoprim Injection**

**Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>2021/08/27</td>
<td>7848288-00003</td>
<td>2021/04/09</td>
</tr>
</tbody>
</table>

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

*Article 57-2 (Enforcement Order Table 9)*

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Aminoethanol</td>
<td>21</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

**Substances Subject to be Indicated Names**

*Article 57 (Enforcement Order Article 18)*

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Aminoethanol</td>
<td>21</td>
</tr>
</tbody>
</table>

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

**Class I Designated Chemical Substances**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-aminoethanol</td>
<td>20</td>
<td>7.6</td>
</tr>
</tbody>
</table>

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Corrosive substances (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)
Aviation Law
Corrosive substances (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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: yyyy/mm/dd

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
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-
centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN