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

Sulfamethoxazole / Trimethoprim Injection Formulation

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

1.1 Product identifier
   Trade name: Sulfamethoxazole / Trimethoprim Injection 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
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone: 353-51-601000
   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)
   Skin corrosion, Sub-category 1B: H314: Causes severe skin burns and eye damage.
   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 - single exposure, Category 3: H335: May cause respiratory irritation.
   Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   - : 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 through prolonged or repeated exposure.
- H410: Very toxic 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:**
- 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.
- 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.
- P391: Collect spillage.

Hazardous components which must be listed on the label:
- Ethanolamine
- Trimethoprim

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. 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>Eye Irrit. 2; H319</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
</tbody>
</table>
### 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 ad-

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>225-248-9</th>
<th>Aquatic Acute 1; H400</th>
<th>Aquatic Chronic 1; H410</th>
<th>&gt;= 10 - &lt; 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sulfamethoxazole</strong></td>
<td></td>
<td>723-46-6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>211-963-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethanolamine</strong></td>
<td></td>
<td>141-43-5</td>
<td>Acute Tox. 4; H302</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>205-483-3</td>
<td>Acute Tox. 4; H332</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>603-030-00-8</td>
<td>Acute Tox. 4; H312</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B; H314</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3; H335</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3; H412</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;= 5 % STOT SE 3; H335</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Acute oral toxicity: 1.089 mg/kg</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Acute inhalation toxicity (vapour): 11 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute dermal toxicity: 1.018 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trimethoprim</strong></td>
<td></td>
<td>738-70-5</td>
<td>Acute Tox. 4; H302</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>212-006-2</td>
<td>Repr. 2; H361d</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Bone marrow)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 2; H411</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
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. 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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: 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.

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products :
- Nitrogen oxides (NOx)
- Sulphur oxides
- Carbon 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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 dis-
posal 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.

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: 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.

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. Keep in a cool, well-ventilated place. 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
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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 of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>TWA</td>
<td>OEB 2 (≥ 100 &lt; 1000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>TWA</td>
<td>1 ppm 2.5 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1 ppm 2.5 mg/m³</td>
<td>2006/15/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm 7.6 mg/m³</td>
<td>2006/15/EC</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>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<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>Ethanolamine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>3.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.24 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>3.75 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanolamine</td>
<td>Fresh water</td>
<td>0.085 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.028 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0085 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.434 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.0434 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
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.
Laboratory operations do not require special containment.

**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

**Skin and body protection**
- Work uniform or laboratory coat.

**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 14387
- Filter type: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic 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
- **Initial boiling point and boiling range**: 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
- **Flash point**: No data available
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Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : 9.5 - 10.5
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
Relative density : No data available
Density : 1,050 - 1,230 g/cm³
Relative vapour density : No data available
Particle characteristics
  Particle size : Not applicable

9.2 Other information
  Explosives : Not explosive
  Oxidizing properties : The substance or mixture is not classified as oxidizing.
  Evaporation rate : No data available
  Molecular weight : No data available

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
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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 hazard classes as defined in Regulation (EC) No 1272/2008

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 toxicity estimate: 1.089 mg/kg
Method: Calculation method

Acute inhalation toxicity:
Acute toxicity estimate: 11 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement
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**Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>27.08.2021</td>
<td>7858245-00004</td>
<td>09.04.2021</td>
<td>03.03.2021</td>
</tr>
</tbody>
</table>

Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

**Acute dermal toxicity**
LD50 (Rabbit, female): 1.018 mg/kg

Acute toxicity estimate: 1.018 mg/kg
Method: Calculation method

**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)
### Genotoxicity in vitro

**Sulfamethoxazole:**
- **Test Type:** Bacterial reverse mutation assay (AMES)
  - Result: negative

**Ethanolamine:**
- **Test Type:** Bacterial reverse mutation assay (AMES)
  - Result: negative

**Trimethoprim:**
- **Test Type:** Bacterial reverse mutation assay (AMES)
  - Result: negative

### Genotoxicity in vivo

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

**Ethanolamine:**
- **Test Type:** Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Humans
  - Result: negative

**Trimethoprim:**
- **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: Embryofetal 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
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</tbody>
</table>

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 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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Sulfamethoxazole / Trimethoprim Injection Formulation**

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**Assessment**: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**Experience with human exposure**

**Components**: 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

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

Trimethoprim:
- Toxicsity 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

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

Ethanolamine:
- Biodegradability: Result: Readily biodegradable.
- Biodegradation: > 90 %
12.3 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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.2 UN proper shipping name

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<td>ETHANOLAMINE, SOLUTION</td>
<td>ETHANOLAMINE, SOLUTION</td>
<td>ETHANOLAMINE SOLUTION (Sulfamethoxazole)</td>
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14.3 Transport hazard class(es)

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14.4 Packing group

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<td>ADR</td>
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</table>
### Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

### 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.

### Maritime transport in bulk according to IMO instruments

- **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: Number on list 3

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


<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
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<tr>
<td>100 t</td>
<td>200 t</td>
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</table>

E1 ENVIRONMENTAL HAZARDS

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:

- DSL: not determined
- AICS: 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.

Full text of H-statements

- H302: Harmful if swallowed.
- H312: Harmful in contact with skin.
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H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H322 : Harmful if inhaled.
H335 : May cause respiratory irritation.
H362 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2006/15/EC : Europe. Indicative occupational exposure limit values
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2006/15/EC / TWA : Limit Value - eight hours
2006/15/EC / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure limit

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; AIIC - Australian Inventory of Industrial Chemicals; 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 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; 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 sub-
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stance; 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; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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<th>Classification procedure:</th>
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<tbody>
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<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
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<tr>
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<td>H335</td>
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<td>STOT RE 2</td>
<td>H373</td>
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<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
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<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
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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