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

Sulfadiazine (40%) / Trimethoprim (8%) Liquid
Formulation

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

1.1 Product identifier
Trade name : Sulfadiazine (40%) / Trimethoprim (8%) Liquid 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 1A H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1 H318: Causes serious eye damage.
Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 :
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine (40%) / Trimethoprim (8%) Liquid
Formulation

Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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.

Supplemental Hazard Statements : EUH071 Corrosive to the respiratory tract.

Precautionary statements : Prevention:
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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>200-685-8</td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute oral toxicity: 1,500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>212-006-2</td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411</td>
<td>8</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>011-002-00-6</td>
<td></td>
<td>Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH014, EUH071</td>
<td>5.5</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 advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

If inhaled: If inhaled, remove to fresh air. 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 allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Corrosive to the respiratory tract. Causes severe burns.
Causes digestive tract burns. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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 firefighting : Exposure to combustion products may be a hazard to health.
Hazardous combustion products : Carbon oxides
Metal oxides

5.3 Advice for firefighters
Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

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

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/PERSOANL 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
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

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<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>Sulfadiazine</td>
<td>68-35-9</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</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>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>OELV - 15 min (STEL)</td>
<td>2 mg/m³</td>
<td>IE OEL</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>Sodium hydroxide</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>1 mg/m³</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 I.S. EN 143

Filter type: Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>suspension</td>
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<tr>
<td>Colour</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
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<tr>
<td>Auto-ignition temperature</td>
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<td>Decomposition temperature</td>
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<td>pH</td>
<td>10.0 - 10.5</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
## Sulfadiazine (40%) / Trimethoprim (8%) Liquid Formulation

**Version**: 9.6  
**Revision Date**: 27.08.2021  
**SDS Number**: 512105-00018  
**Date of last issue**: 03.03.2021  
**Date of first issue**: 10.02.2016

- **octanol/water**  
- **Vapour pressure**: No data available  
- **Relative density**: No data available  
- **Density**: No data available  
- **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

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
Not classified as a reactivity hazard.

#### 10.2 Chemical stability
Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

- **Hazardous reactions**: Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

- **Conditions to avoid**: None known.

#### 10.5 Incompatible materials

- **Materials to avoid**: Oxidizing agents  
  - Acids

#### 10.6 Hazardous decomposition products
No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

- **Information on likely routes of exposure**:  
  - Inhalation  
  - Skin contact  
  - Ingestion  
  - Eye contact
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine (40%) / Trimethoprim (8%) Liquid Formulation

Acute toxicity
Not classified based on available information.

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

Components:
Sulfadiazine:
Acute oral toxicity : LD50 (Mouse): 1,500 mg/kg
Acute toxicity estimate: 1,500 mg/kg
Method: Calculation method

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Acute toxicity (other routes of administration) : LD50 (Rat): 880 mg/kg
Application Route: Intravenous
LD50 (Mouse): 180 mg/kg
Application Route: Intravenous

Trimethoprim:
Acute oral toxicity : LD50 (Rat): 1,500 - 5,300 mg/kg
LD50 (Mouse): 1,910 - 7,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 400 - 500 mg/kg
Application Route: Intraperitoneal
LD50 (Dog): 90 mg/kg
Application Route: Intravenous
LD50 (Mouse): 132 mg/kg
Application Route: Intravenous

Sodium hydroxide:
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation
Causes severe burns.

Components:
Sulfadiazine:
Result : Skin irritation
Remarks : Based on data from similar materials
Sodium hydroxide:
Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation
Causes serious eye damage.

Components:
Sulfadiazine:
Species : Rabbit
Result : Irritation to eyes, reversing within 7 days
Remarks : Based on data from similar materials

Sodium hydroxide:
Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:
Sulfadiazine:
Test Type : Maximisation Test
Species : Guinea pig
Result : Not a skin sensitizer.
Remarks : Based on data from similar materials

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:
Sulfadiazine:
Genotoxicity in vitro:

- **Test Type**: Bacterial reverse mutation assay (AMES)
- **Result**: negative
- **Remarks**: Based on data from similar materials

- **Test Type**: Chromosomal aberration
  - **Test system**: Chinese hamster ovary cells
  - **Result**: negative
  - **Remarks**: Based on data from similar materials

**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.

Reproductive toxicity

Suspected of damaging the unborn child.

**Components**:

**Sulfadiazine**:

Effects on foetal development:

- **Test Type**: Development
  - **Species**: Mouse
  - **Application Route**: Oral
  - **General Toxicity Maternal**: NOAEL: 1,000 mg/kg body weight
  - **Result**: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

**Trimethoprim**:

Effects on fertility:

- **Test Type**: Fertility
  - **Species**: Rat
  - **Application Route**: Oral
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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.
Corrosive to the respiratory tract.

**Components:**

**Sulfadiazine:**
Assessment: May cause respiratory irritation.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
Components:

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

Repeated dose toxicity

Components:

Trimethoprim:
Species: Rat
NOAEL: 100 mg/kg
LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Bone marrow, Liver, Pituitary gland, Thyroid

Species: Rat
NOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Bone marrow

Species: Dog
NOAEL: 2.5 mg/kg
LOAEL: 45 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Blood, Thyroid

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

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.

Experience with human exposure

Components:

Sulfadiazine:
General Information: May cause eye, skin, and respiratory tract irritation.
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:

Sulfadiazine:
- Toxicity to fish
  - LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates
  - EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants
  - EC50 (Anabaena flos-aquae): 17 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Anabaena flos-aquae): 3.9 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - EC50 (Microcystis aeruginosa (blue-green algae)): 0.135 mg/l
  - Exposure time: 7 Days
  - Method: ISO 8692

M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms
- EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
- NOEC: 1,000 mg/l
  - Exposure time: 3 h
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Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 6.2 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1

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 (Pseudokirchneriiella subcapitata (microalgae)): 80.3 mg/l
    Exposure time: 72 h
  - NOEC (Pseudokirchneriiella 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:

Sulfadiazine:
- Biodegradability: Not readily biodegradable.
  Biodegradation: 0%
  Exposure time: 28 d
  Method: OECD Test Guideline 314
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12.3 Bioaccumulative potential

Components:

Sulfadiazine:
Partition coefficient: n-octanol/water : log Pow: 0.12

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

Sulfadiazine (40%) / Trimethoprim (8%) Liquid
Formulation

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Date of first issue: 10.02.2016

ADN : UN 1760
ADR : UN 1760
RID : UN 1760
IMDG : UN 1760
IATA : UN 1760

14.2 UN proper shipping name

ADN : CORROSIVE LIQUID, N.O.S.
      (Sodium hydroxide)
ADR : CORROSIVE LIQUID, N.O.S.
      (Sodium hydroxide)
RID : CORROSIVE LIQUID, N.O.S.
      (Sodium hydroxide)
IMDG : CORROSIVE LIQUID, N.O.S.
      (Sodium hydroxide, Sulfadiazine)
IATA : Corrosive liquid, n.o.s.
      (Sodium hydroxide)

14.3 Transport hazard class(es)

ADN : 8
ADR : 8
RID : 8
IMDG : 8
IATA : 8

14.4 Packing group

ADN
Packing group : I
Classification Code : C9
Hazard Identification Number : 88
Labels : 8

ADR
Packing group : I
Classification Code : C9
Hazard Identification Number : 88
Labels : 8
Tunnel restriction code : (E)

RID
Packing group : I
Classification Code : C9
Hazard Identification Number : 88
Labels : 8

IMDG
Packing group : I
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine (40%) / Trimethoprim (8%) Liquid
Formulation

Version 9.6  Revision Date: 27.08.2021  SDS Number: 512105-00018  Date of last issue: 03.03.2021
Date of first issue: 10.02.2016

Labels  : 8
EmS Code  : F-A, S-B

IATA (Cargo)
Packing instruction (cargo aircraft)  : 854
Packing group  : I
Labels  : Corrosive

IATA (Passenger)
Packing instruction (passenger aircraft)  : 850
Packing group  : I
Labels  : Corrosive

14.5 Environmental hazards

ADN
Environmentally hazardous  : yes

ADR
Environmentally hazardous  : yes

RID
Environmentally hazardous  : yes

IMDG
Marine pollutant  : yes

14.6 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.

14.7 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
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
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine (40%) / Trimethoprim (8%) Liquid Formulation


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

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

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

<table>
<thead>
<tr>
<th>H-Statement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H290</td>
<td>May be corrosive to metals.</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation.</td>
</tr>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>EUH014</td>
<td>Reacts violently with water.</td>
</tr>
<tr>
<td>EUH071</td>
<td>Corrosive to the respiratory tract.</td>
</tr>
</tbody>
</table>

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox.</td>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Aquatic Acute</td>
<td>Short-term (acute) aquatic hazard</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td>Eye Dam.</td>
<td>Serious eye damage</td>
</tr>
</tbody>
</table>
Sulfadiazine (40%) / Trimethoprim (8%) Liquid Formulation

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<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit.</td>
<td>Eye irritation</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Met. Corr.</td>
<td>Corrosive to metals</td>
<td>ADN</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
<td>ADN</td>
</tr>
<tr>
<td>Resp. Sens.</td>
<td>Respiratory sensitisation</td>
<td>ADN</td>
</tr>
<tr>
<td>Skin Corr.</td>
<td>Skin corrosion</td>
<td>ADN</td>
</tr>
<tr>
<td>Skin Irrit.</td>
<td>Skin irritation</td>
<td>ADN</td>
</tr>
<tr>
<td>STOT RE</td>
<td>Specific target organ toxicity - repeated exposure</td>
<td>ADN</td>
</tr>
<tr>
<td>STOT SE</td>
<td>Specific target organ toxicity - single exposure</td>
<td>ADN</td>
</tr>
<tr>
<td>IE OEL</td>
<td>Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1</td>
<td>ADN</td>
</tr>
<tr>
<td>IE OEL / OELV - 15 min (STEL)</td>
<td>Occupational exposure limit value (15-minute reference period)</td>
<td>ADN</td>
</tr>
</tbody>
</table>

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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Philippines Inventory of Dangerous Substances; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

**Classification of the mixture:**

**Classification procedure:**
Sulfadiazine (40%) / Trimethoprim (8%) Liquid Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Code</th>
<th>Description</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Corr. 1A</td>
<td>H314</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H335</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td></td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td></td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN