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

1.1 Product identifier

Trade name: Sulfadiazine / Trimethoprim Solid 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
Kilsheolan
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 irritation, Category 2
Eye irritation, Category 2
Respiratory sensitisation, Category 1
Reproductive toxicity, Category 2
Specific target organ toxicity - single exposure, Category 3
Specific target organ toxicity - repeated exposure, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361d: Suspected of damaging the unborn child.
H335: May cause respiratory irritation.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms:

Signal word: Danger
Hazard statements:
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- 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.

Precautionary statements:
Prevention:
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:
- Sulfadiazine
- 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.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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.

**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.

For explanation of abbreviations see section 16.
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.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
Causes skin irritation.
Causes serious eye irritation.
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.

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:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
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 dust.
- 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.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- 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

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>Sulfadiazine</td>
<td>68-35-9</td>
<td>TWA</td>
<td>2 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Sulfadiazine / Trimethoprim Solid 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>5.8</td>
<td>27.08.2021</td>
<td>1738927-00014</td>
<td>09.04.2021</td>
<td>08.06.2017</td>
</tr>
</tbody>
</table>

<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>Calcium carbonate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6,36 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>6,1 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1,06 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>6,1 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

**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>Calcium carbonate</td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**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 143
  - Filter type: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- **Physical state**: powder
- **Colour**: light yellow
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling**: No data available
### SAFETY DATA SHEET

**Sulfadiazine / Trimethoprim Solid Formulation**

**Version**: 5.8  
**Revision Date**: 27.08.2021  
**SDS Number**: 1738927-00014  
**Date of last issue**: 09.04.2021  
**Date of first issue**: 08.06.2017

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</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>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**9.2 Other information**

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: Not applicable

**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

Not classified as a reactivity hazard.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine / Trimethoprim Solid Formulation

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

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

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:
Sulfadiazine / Trimethoprim Solid Formulation

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 skin irritation.

Components:
Sulfadiazine:
Result: Skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

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

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.
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:
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
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: 70 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:

Sulfadiazine:
Assessment : May cause respiratory irritation.

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

**Trimethoprim:**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone marrow</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

**Components:**

**Trimethoprim:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>100 mg/kg</td>
<td>300 mg/kg</td>
<td>Oral</td>
<td>6 Months</td>
<td>Bone marrow, Liver, Pituitary gland, Thyroid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>300 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Bone marrow</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>2.5 mg/kg</td>
<td>46 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Blood, Thyroid</td>
</tr>
</tbody>
</table>

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

<table>
<thead>
<tr>
<th>Assessment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

### Experience with human exposure

**Components:**

**Sulfadiazine:**

<table>
<thead>
<tr>
<th>General Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>May cause eye, skin, and respiratory tract irritation.</td>
</tr>
</tbody>
</table>

**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
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
Sulfadiazine / Trimethoprim Solid 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>
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</thead>
<tbody>
<tr>
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<td>08.06.2017</td>
</tr>
</tbody>
</table>

**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 (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:**

**Sulfadiazine:**

- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 0 %
- Exposure time: 28 d
- Method: OECD Test Guideline 314

### 12.3 Bioaccumulative potential

**Components:**

**Sulfadiazine:**

- Partition coefficient: log Pow: 0,12
Sulfadiazine / Trimethoprim Solid Formulation

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

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
### ADN
- **Description**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

### ADR
- **Description**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

### RID
- **Description**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

### IMDG
- **Description**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

### IATA
- **Description**: Environmentally hazardous substance, solid, n.o.s. (Sulfadiazine)

#### 14.3 Transport hazard class(es)

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<th>Mode</th>
<th>Hazard Class</th>
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#### 14.4 Packing group

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<td>RID</td>
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Sulfadiazine / Trimethoprim Solid Formulation

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<tbody>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
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</tbody>
</table>

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**14.5 Environmental hazards**

- **ADN**
  - Environmentally hazardous: yes
- **ADR**
  - Environmentally hazardous: yes
- **RID**
  - Environmentally hazardous: yes
- **IMDG**
  - Marine pollutant: yes
- **IATA (Passenger)**
  - Environmentally hazardous: yes
- **IATA (Cargo)**
  - Environmentally hazardous: 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)**: Not applicable
- **REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59)**: Not applicable
- **REACH - List of substances subject to authorisation (Annex XIV)**: Not applicable
- **Regulation (EC) No 1005/2009 on substances that deplete the ozone layer**: Not applicable
- **Regulation (EU) 2019/1021 on persistent organic pollutants (recast)**: Not applicable
- **Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals**: Not applicable

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

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

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

SECTION 16: Other information

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

Full text of H-Statements
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 : May cause respiratory irritation.
H361d : Suspected of damaging the unborn child.
H372 : 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.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
## SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

### Sulfadiazine / Trimethoprim Solid Formulation

<table>
<thead>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>1738927-00014</td>
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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; ICH - 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 - 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

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

### Classification of the mixture:

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