SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Section 1: Identification

Product name : Sulfadiazine / Trimethoprim Solid Formulation

Manufacturer or supplier's details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

Section 2: Hazard identification

GHS Classification
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2B
Respiratory sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure : Category 3
Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

GHS label elements
Hazard pictograms : 
Signal word : Danger
Hazard statements : H315 + H320 Causes skin and 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 (Bone marrow) through
**Precautionary statements**: 

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- P284 Wear respiratory protection.

**Response:**
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P332 + P313 If skin irritation occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**
- P405 Store locked up.

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

**Other hazards which do not result in classification**

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

### Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>60</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>33.34</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>6.66</td>
</tr>
</tbody>
</table>

### Section 4: First-aid measures

**General advice**: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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. 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.

Most important symptoms and effects, both acute and delayed: Causes skin and 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).

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

Notes to physician: Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

Unsuitable extinguishing media: None known.

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

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.
<table>
<thead>
<tr>
<th>Section 6: Accidental release measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personal precautions, protective equipment and emergency procedures</strong></td>
</tr>
<tr>
<td><strong>Environmental precautions</strong></td>
</tr>
<tr>
<td><strong>Methods and materials for containment and cleaning up</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section 7: Handling and storage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical measures</strong></td>
</tr>
<tr>
<td><strong>Local/Total ventilation</strong></td>
</tr>
<tr>
<td><strong>Advice on safe handling</strong></td>
</tr>
</tbody>
</table>
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.

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

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>WES-TWA</td>
<td>10 mg/m³ (Calcium carbonate)</td>
<td>NZ OEL</td>
</tr>
<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>
</tbody>
</table>

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection Material: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or
### Skin and body protection

| Aerosols | Work uniform or laboratory coat. |

### Section 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<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>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</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>Solubility(ies)</td>
<td>Water solubility No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</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>Viscosity</td>
<td>Viscosity, kinematic Not applicable</td>
</tr>
</tbody>
</table>
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Sulfadiazine / Trimethoprim Solid Formulation

Version 3.0
Revision Date: 27.08.2021
SDS Number: 1737608-00012
Date of last issue: 03.03.2021
Date of first issue: 08.06.2017

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: No data available

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes: 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:
Calcium carbonate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 420
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity: LC50 (Rat): > 3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
### Sulfadiazine:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Route</th>
<th>LD50</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>Mouse</td>
<td>1,500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Rat</td>
<td>&gt; 5,000 mg/kg</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>Rat</td>
<td>880 mg/kg</td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>180 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

### Trimethoprim:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Route</th>
<th>LD50</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>Rat</td>
<td>1,500 - 5,300 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>1,910 - 7,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>Rat</td>
<td>400 - 500 mg/kg</td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>90 mg/kg</td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>132 mg/kg</td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation

Causes skin irritation.

**Components:**

**Calcium carbonate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Sulfadiazine:**

<table>
<thead>
<tr>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation

Causes eye irritation.

**Components:**

**Calcium carbonate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>
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**:

Calcium carbonate:
- **Test Type**: Local lymph node assay (LLNA)
- **Exposure routes**: Skin contact
- **Species**: Mouse
- **Method**: OECD Test Guideline 429
- **Result**: negative

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.

Chronic toxicity

Germ cell mutagenicity
- Not classified based on available information.

**Components**:

Calcium carbonate:
- **Genotoxicity in vitro**
  - **Test Type**: Bacterial reverse mutation assay (AMES)
    - **Method**: OECD Test Guideline 471
    - **Result**: negative
  
  Test Type: Chromosome aberration test in vitro
  - **Method**: OECD Test Guideline 473
  - **Result**: negative

  Test Type: In vitro mammalian cell gene mutation test
  - **Method**: OECD Test Guideline 476
  - **Result**: negative
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### 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>3.0</td>
<td>27.08.2021</td>
<td>1737608-00012</td>
<td>03.03.2021</td>
<td>08.06.2017</td>
</tr>
</tbody>
</table>

### Sulfadiazine:

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

**Genotoxicity in vivo**
- Test Type: Micronucleus test
  - Species: Rat
  - Result: negative

### Trimethoprim:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Chromosomal aberration
  - Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: negative

**Genotoxicity in vivo**
- Test Type: Chromosomal aberration
  - Species: Humans
  - Result: negative

### Carcinogenicity
- Not classified based on available information.

### Reproductive toxicity
- Suspected of damaging the unborn child.

### Components:

#### Calcium carbonate:

**Effects on fertility**
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 422
  - Result: negative

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

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: 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:

Sulfadiazine:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs (Bone marrow) 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:

Calcium carbonate:

Species: Rat
NOAEL: > 1,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days
Method: OECD Test Guideline 422

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
LOAEL: 45 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Bone marrow

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

Aspiration toxicity

Not classified based on available information.
Experience with human exposure

Components:

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

Ecotoxicity

Components:

Calcium carbonate:
Toxicity to fish: LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201

Toxicity to microorganisms: NOEC: 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

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: EC50 (Daphnia magna (Water flea)): > 100 mg/l
### aquatic invertebrates

Exposure time: 48 h  
Method: OECD Test Guideline 202

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>(Anabaena flos-aquae)</td>
<td>17 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

NOEC (Anabaena flos-aquae): 3.9 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>(Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: ISO 8692</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>(Microcystis aeruginosa (blue-green algae))</td>
<td>0.135 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>7 Days</td>
<td></td>
</tr>
</tbody>
</table>

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

NOEC (Daphnia magna (Water flea)): 6.2 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 1,000 mg/l</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 h</td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
<td></td>
</tr>
</tbody>
</table>

NOEC: 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Trimethoprim:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50</td>
<td>(Pimephales promelas (fathead minnow))</td>
<td>100 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to fish

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>(Daphnia magna Straus)</td>
<td>92 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>48 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>(Pseudokirchneriella subcapitata (microalgae))</td>
<td>80.3 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l  
Exposure time: 72 h
EC50 (Anabaena flos-aquae): 253 mg/l
Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity):

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

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

Persistence and degradability

Components:

Sulfadiazine:

Biodegradability:

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

Bioaccumulative potential

Components:

Sulfadiazine:

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

Trimethoprim:

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

Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods:

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

Section 14: Transport information

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Sulfadiazine)

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

National Regulations

NZS 5433
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)

Class: 9
Packing group: III
Labels: 9
Hazchem Code: 2Z

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.

Section 15: Regulatory information

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

Sulfadiazine / Trimethoprim Solid Formulation

Version 3.0  Revision Date: 27.08.2021  SDS Number: 1737608-00012  Date of last issue: 03.03.2021
Date of first issue: 08.06.2017

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

<table>
<thead>
<tr>
<th>AICS</th>
<th>not determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information

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

Date format: dd.mm.yyyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>NZ OEL / WES-TWA</th>
<th>Workplace Exposure Standard - Time Weighted average</th>
</tr>
</thead>
</table>

NZ OEL: New Zealand, Workplace Exposure Standards for Atmospheric Contaminants

AZIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperatures; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

NZ / EN