SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Version: 5.0  Revision Date: 2020/03/23  SDS Number: 1737632-00009  Date of last issue: 2019/09/13
Date of first issue: 2017/06/08

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Sulfadiazine / Trimethoprim Solid Formulation

Supplier’s company name, address and phone number

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Category 3</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 2 (Bone marrow)</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard</td>
<td>Category 1</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

GHS label elements

Hazard pictograms:

- Skin corrosion/irritation
- Serious eye damage
- Respiratory sensitisation

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 (Bone marrow) through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- 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.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.

Storage:
- P405 Store locked up.

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

Other hazards which do not result in classification:
Important symptoms and outlines of the emergency assumed: May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS
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| Substance / Mixture | Mixture |

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>60</td>
<td>1-122</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>33.34</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>6.66</td>
<td></td>
</tr>
</tbody>
</table>

**4. FIRST AID MEASURES**

**General advice**

In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled**

If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

**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 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).

**Protection of first-aiders**

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

**Notes to physician**

Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES**

**Suitable extinguishing media**

Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuitable extinguishing media</td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>None known.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>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.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Metal oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>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.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</td>
</tr>
</tbody>
</table>

### 7. HANDLING AND STORAGE

**Handling**

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust</td>
</tr>
</tbody>
</table>
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Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- 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.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
- Oxidizing agents

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage:
- 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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>OEL-M (Respirable dust)</td>
<td>2 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>8 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>

Further information:
- Class 3 Dust

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<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>: 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal protective equipment</td>
<td>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 Material : Chemical-resistant gloves</td>
</tr>
<tr>
<td>Eye protection</td>
<td>: 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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>: Work uniform or laboratory coat.</td>
</tr>
</tbody>
</table>

9. 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 |
| Boiling point, initial boiling point and boiling range | : No data available |
| Flammability (solid, gas) | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Flash point | : No data available |
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Decomposition temperature : No data available
pH : No data available
Evaporation rate : Not applicable
Auto-ignition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : Not applicable
Density and / or relative density
  Relative density : No data available
Density : No data available
Relative vapour density : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle characteristics
  Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
  Inhalation
  Skin contact
  Ingestion
  Eye contact
Acute toxicity
Not classified based on available information.

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

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:
Acute oral toxicity: LD50 (Mouse): 1,500 mg/kg

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

Skin corrosion/irritation
Causes skin irritation.

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td></td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td></td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td></td>
<td></td>
<td>Irritation to eyes, reversing within 7 days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>Maximisation Test</td>
<td></td>
<td>Guinea pig</td>
<td></td>
<td>Not a skin sensitizer.</td>
<td></td>
</tr>
</tbody>
</table>
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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:

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

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
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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>45 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Thyroid</td>
</tr>
</tbody>
</table>

**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

**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: NOELR (Pseudokirchneriella subcapitata (green algae)): 50
<table>
<thead>
<tr>
<th>Sulfadiazine / Trimethoprim Solid Formulation</th>
</tr>
</thead>
</table>

**Version** | **Revision Date** | **SDS Number** | **Date of last issue** | **Date of first issue** |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>2020/03/23</td>
<td>1737632-00009</td>
<td>2019/09/13</td>
<td>2017/06/08</td>
</tr>
</tbody>
</table>

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

**Toxicity to algae/aquatic plants**
- EC50: > 100 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**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

**M-Factor (Acute aquatic toxicity)**
- 1

**Toxicity to daphnia and other aquatic invertebrates (Chronic)**
- NOEC (Daphnia magna (Water flea)): 6.2 mg/l
- Exposure time: 21 d

**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
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</tr>
</tbody>
</table>

**Toxicity to microorganisms**

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

**Sulfadiazine**

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

**Trimethoprim**

- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
  - **Exposure time**: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna Straus): 92 mg/l
  - **Exposure time**: 48 h

- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l
  - **Exposure time**: 72 h

  - **NOEC (Pseudokirchneriella subcapitata (green algae))**: 16 mg/l
    - **Exposure time**: 72 h

  - **EC50 (Anabaena flos-aquae)**: 253 mg/l
    - **Exposure time**: 72 h

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

- **Toxicity to fish (Chronic toxicity)**: NOEC (Zebrafish): 0.157 mg/l
  - **Exposure time**: 21 d

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 6 mg/l
  - **Exposure time**: 21 d

**Persistence and degradability**

**Components**

**Sulfadiazine**

- **Biodegradability**: Not readily biodegradable.
  - **Biodegradation**: 0 %
  - **Exposure time**: 28 d
  - **Method**: OECD Test Guideline 314
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Version: 5.0
Revision Date: 2020/03/23
SDS Number: 1737632-00009
Date of last issue: 2019/09/13
Date of first issue: 2017/06/08

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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
Class: 9
Packing group: III
Labels: Miscellaneous

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

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SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Version 5.0  Revision Date: 2020/03/23  SDS Number: 1737632-00009  Date of last issue: 2019/09/13

UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

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

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable
Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Classified as marine pollutant

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

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

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Date of first issue: 2017/06/08

DSL : not determined
IECSC : not determined

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: yyyy/mm/dd

Full text of other abbreviations

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

AICS - Australian Inventory of Chemical Substances; 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.

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