SAFETY DATA SHEET  
according to the Hazardous Products Regulations

Sulfadiazine / Trimethoprim Solid Formulation

Version 5.1  
Revision Date: 09/30/2023  
SDS Number: 1737640-00019  
Date of last issue: 04/04/2023  
Date of first issue: 06/08/2017

SECTION 1. IDENTIFICATION

Product name: Sulfadiazine / Trimethoprim Solid Formulation  
Other means of identification: No data available

Manufacturer or supplier’s details

Company name of supplier: Merck & Co., Inc  
Address: 126 E. Lincoln Avenue, Rahway, New Jersey U.S.A. 07065  
Telephone: 908-740-4000  
Emergency telephone: 1-908-423-6000  
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product  
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Skin irritation: Category 2  
Eye irritation: Category 2B  
Respiratory sensitization: Category 1  
Reproductive toxicity: Category 2  
Specific target organ toxicity - single exposure: Category 3  
Specific target organ toxicity - repeated exposure: Category 1 (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.  
H372 Causes damage to organs (Bone marrow) through prolonged or repeated exposure.
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.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection and 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 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 attention.
P332 + P313 IF skin irritation occurs: Get medical attention.
P337 + P313 IF eye irritation persists: Get medical attention.
P342 + P311 IF experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Carbonic acid calcium salt</td>
<td>471-34-1</td>
<td>60</td>
</tr>
<tr>
<td>sulfadiazine</td>
<td>Benzenesulfonamide, 4-amino-N-2-pyrimidinyl-</td>
<td>68-35-9</td>
<td>33.34</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>2,4-Pyrimidinediamine, 5-[(3,4,5-</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. Causes 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

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: 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.
- Evacuate area.

**Special protective equipment for fire-fighters**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**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.

**Methods and materials for containment and cleaning up**
- Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.
- Add excess liquid to allow the material to enter into solution.
- Soak up with inert absorbent material.
- 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.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

**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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.

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.

Conditions for safe storage:
Keep in properly labeled 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
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<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>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 mg/m³</td>
<td>CA BC 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>
Sulfadiazine / Trimethoprim Solid Formulation

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 aerosols.

Skin and body protection
Work uniform or laboratory coat.

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 decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

 SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
powder

Color
light yellow

Odor
No data available

Odor Threshold
No data available

pH
No data available

Melting point/freezing point
No data available

Initial boiling point and boiling range
No data available

Flash point
No data available

Evaporation rate
Not applicable

Flammability (solid, gas)
May form explosive dust-air mixture during processing,
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Sulfadiazine / Trimethoprim Solid Formulation

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
   Viscosity, kinematic : Not applicable

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

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):

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Rat)</td>
<td>Intraperitoneal</td>
<td>400 - 500 mg/kg</td>
</tr>
<tr>
<td>LD50 (Dog)</td>
<td>Intravenous</td>
<td>90 mg/kg</td>
</tr>
<tr>
<td>LD50 (Mouse)</td>
<td>Intravenous</td>
<td>132 mg/kg</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>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<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>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**Sulfadiazine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 7 days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

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

**Components:**

**Calcium carbonate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
</tr>
</tbody>
</table>
Species: Mouse
Method: OECD Test Guideline 429
Result: negative

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

**Trimethoprim:**
Test Type: Maximization Test
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
### Genotoxicity in vivo

- **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

#### 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 fetal development**  
  **Test Type:** Embryo-fetal development  
  **Species:** Rat  
  **Application Route:** Ingestion  
  **Method:** OECD Test Guideline 414  
  **Result:** negative

**Sulfadiazine:**
- **Effects on fetal 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 fetal 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
Causes 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
- LOAEL: 300 mg/kg
- Application Route: Oral
- Exposure time: 3 Months
- Target Organs: Bone marrow

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

Aspiration toxicity
Not classified based on available information.

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

Toxicity to algae/aquatic plants:
- NOEC (Pseudokirchneriella subcapitata (microalgae)): 16 mg/l
  Exposure time: 72 h

Trimethoprim:
- 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

- Toxicity to microorganisms:
  EC10: 16.7 mg/l
  Exposure time: 3 hrs
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
Sulfadiazine / Trimethoprim Solid Formulation

EC50: > 1,000 mg/l
Exposure time: 3 hrs
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

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

Trimethoprim:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 4 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Result: Not inherently biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 302B

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: Do not dispose of waste into sewer.
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.
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
Environmentally hazardous : yes

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.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(sulfadiazine)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(sulfadiazine)
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

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

- CA BC OEL: Canada. British Columbia OEL
- CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- CA AB OEL / TWA: 8-hour Occupational exposure limit
- CA BC OEL / TWA: 8-hour time weighted average
- CA BC OEL / STEL: short-term exposure limit
- CA QC OEL / TWAEV: Time-weighted average exposure value

AIIC - 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 Civil Aviation Organization; 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 Standardisation; 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, Bioaccumul-
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Sulfadiazine / Trimethoprim Solid Formulation

Version 5.1  Revision Date: 09/30/2023  SDS Number: 1737640-00019  Date of last issue: 04/04/2023  Date of first issue: 06/08/2017

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

Revision Date: 09/30/2023  Date format: mm/dd/yyyy

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.

CA / Z8