SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadiazine / Trimethoprim Solid Formulation

Manufacturer or supplier's details

Company : MSD
Address : Rua Coronel Bento Soares, 530
          Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral) : Category 5
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 2 (Bone marrow)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :
**SAFETY DATA SHEET**

**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>6.3</td>
<td>27.08.2021</td>
<td>1737639-00012</td>
<td>03.03.2021</td>
<td>08.06.2017</td>
</tr>
</tbody>
</table>

**Signal Word**

: Danger

**Hazard Statements**

: H303 May be harmful if swallowed.
  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 prolonged or repeated exposure.
  H410 Very toxic to aquatic life with long lasting effects.

**Precautionary Statements**

: **Prevention:**
  P201 Obtain special instructions before use.
  P260 Do not breathe dust.
  P273 Avoid release to the environment.
  P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

: P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
  P391 Collect spillage.

**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

**Substance / Mixture**: Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>Acute toxicity (Oral), Category 4 Skin irritation, Category 2 Eye irritation, Category 2B Respiratory sensitization, Category 1 Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>33.34</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>Acute toxicity (Oral), Category 4</td>
<td>6.66</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

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: May be harmful if swallowed. 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

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

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.
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 spills cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 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.

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 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSOANAL 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>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 aerosols.

Skin and body protection : Work uniform or laboratory coat.

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, handling or other means.
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 reac-
tions : 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
May be harmful if swallowed.

Product:
Acute oral toxicity : Acute toxicity estimate: 2.814 mg/kg
  Method: Calculation method
Components:

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:

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

Serious eye damage/eye irritation
Causes eye irritation.

Components:

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

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:

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
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Sulfadiazine:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative
Remarks: Based on data from similar materials

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

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Result: negative
Test Type: Chromosomal aberration
Species: Humans
Result: negative
Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Sulfadiazine:
Effects on 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: 15 mg/kg body weight
Result: Embryotoxic effects.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1,7 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects.

Test Type: Development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight

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:
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:

Sulfadiazine:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

EC50 (Anabaena flos-aquae): 17 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 3,9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l
Exposure time: 7 Days
Method: ISO 8692

M-Factor (Acute aquatic toxicity): 1

Toxicity to 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

Date of last issue: 03.03.2021
Date of first issue: 08.06.2017
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Version 6.3  Revision Date: 27.08.2021  SDS Number: 1737639-00012  Date of last issue: 03.03.2021

Date of first issue: 08.06.2017

M-Factor (Chronic aquatic toxicity): 1

Toxicity to microorganisms:

EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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 (Water flea)): 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:

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.

Domestic regulation

ANTT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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
National List of Carcinogenic Agents for Humans -(LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Calcium carbonate

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
SAFETY DATA SHEET

Sulfadiazine / Trimethoprim Solid Formulation

Version 6.3  Revision Date: 27.08.2021  SDS Number: 1737639-00012  Date of last issue: 03.03.2021

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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