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

Telefax: 908-735-1496

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
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Version 6.0  Revision Date: 23.03.2020  SDS Number: 1737639-00009  Date of last issue: 13.09.2019
Date of first issue: 08.06.2017

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:
- Person symbol
- Exclamation mark
- Plant symbol

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.
H337 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), Skin irritation, Eye irritation, Respiratory sensitization, Specific target organ toxicity</td>
<td>33,34</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: 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
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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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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.
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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. 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. 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/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

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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
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

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
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: 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:

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  
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.
- **Ingestion:** Target Organs: Bone marrow
  - Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

**trimethoprim:**
- Ingestion:
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

**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
M-Factor (Chronic aquatic toxicity):
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:**
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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
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.

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

International Regulations

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

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

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Version 6.0  Revision Date: 23.03.2020  SDS Number: 1737639-00009  Date of last issue: 13.09.2019

Full text of other abbreviations

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 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 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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