SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sulfapyridine Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 3
Skin sensitization: Category 1
Reproductive toxicity: Category 1A
Specific target organ toxicity - single exposure (Oral): Category 1

GHS label elements
Hazard pictograms:
- Skull and crossbones
- An exclamation mark

Signal Word: Danger

Hazard Statements:
H301 Toxic if swallowed.
H317 May cause an allergic skin reaction.
H360F May damage fertility.
H370 Causes damage to organs if swallowed.

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/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/doctor.
P333 + P313 IF skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form combustible dust concentrations in air during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>Sulfapyridine</td>
<td>144-83-2</td>
<td>&gt;= 10 - &lt; 20</td>
<td></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.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Call a physician or poison control center immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and : Toxic if swallowed.
May cause an allergic skin reaction.
SAFETY DATA SHEET

Sulfapyridine Formulation

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:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon 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.
SAFETY DATA SHEET

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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, fume, gas, mist, vapors or spray.
Do not swallow.
Avoid contact with 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.
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.
Contaminated work clothing should not be allowed out of the workplace.
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.
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</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Compounds</th>
<th>Form of exposure</th>
<th>Permissible concentration</th>
<th>Source / guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>VLE-PPT (Mist)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sulfapyridine</td>
<td>144-83-2</td>
<td>TWA</td>
<td>0.25 mg/m³ (OEB 2)</td>
</tr>
</tbody>
</table>

**Further information:** DSEN  
Wipe limit 0.1 mg/100 cm² Internal

**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: Combined particulates and organic vapor type  
Hand protection: 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:** solid  
**Color:** No data available  
**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:** Not applicable  
**Evaporation rate:** Not applicable
Flammability (solid, gas) : May form combustible dust concentrations in air 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.

Molecular weight : No data available

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 combustible dust concentrations in air 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

Toxic if swallowed.

**Product:**

- Acute oral toxicity: Acute toxicity estimate: 158 mg/kg
  Method: Calculation method

**Components:**

- Petrolatum:
  - Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
    Method: OECD Test Guideline 401
    Remarks: Based on data from similar materials
  - Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
    Method: OECD Test Guideline 402
    Assessment: The substance or mixture has no acute dermal toxicity
    Remarks: Based on data from similar materials

- Sulfapyridine:
  - Acute oral toxicity: LD50 (Rat): 15.8 mg/kg

Skin corrosion/irritation

Not classified based on available information.

**Components:**

- Petrolatum:
  - Species: Rabbit
  - Method: OECD Test Guideline 404
  - Result: No skin irritation
  - Remarks: Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

**Components:**

- Petrolatum:
  - Species: Rabbit
  - Method: OECD Test Guideline 405
  - Result: No eye irritation
  - Remarks: Based on data from similar materials
Respiratory or skin sensitization

Skin sensitization

- May cause an allergic skin reaction.

Respiratory sensitization

- Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Petrolatum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type:</td>
</tr>
<tr>
<td>Routes of exposure:</td>
</tr>
<tr>
<td>Species:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Remarks:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sulfapyridine:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment:</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity

- Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Petrolatum:</th>
</tr>
</thead>
</table>
| Genotoxicity in vitro: | Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th>Sulfapyridine:</th>
</tr>
</thead>
</table>
| Genotoxicity in vitro: | Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: positive  
Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster cells  
Result: negative |

| Genotoxicity in vivo: | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Cell type: Bone marrow  
Result: negative |
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Sulfapyridine Formulation

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity:
Not classified based on available information.

Components:

Petrolatum:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Sulfapyridine:
Carcinogenicity - Assessment: No data available

Reproductive toxicity:
May damage fertility.

Components:

Petrolatum:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Sulfapyridine:
Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

STOT-single exposure:
Causes damage to organs if swallowed.

Components:

Sulfapyridine:
Routes of exposure Assessment: Oral
Shown to produce significant health effects in animals at concentrations of 300 mg/kg bw or less.
STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Petrolatum:
| Species  | Rat          |
| NOAEL    | 5,000 mg/kg  |
| Application Route | Ingestion |
| Exposure time | 2 y         |

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Sulfapyridine:
| Skin contact | Symptoms: Sensitization |
| Ingestion    | Symptoms: Gastrointestinal disturbance |
|             | Symptoms: Sensitivity to light |
|             | Symptoms: Headache |
|             | Symptoms: hepatitis |
|             | Symptoms: Stevens-Johnson syndrome |

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
| Toxicity to fish | LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l |
| Exposure time    | 96 h |
| Test substance   | Water Accommodated Fraction |
| Method           | OECD Test Guideline 203 |
| Remarks          | Based on data from similar materials |

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l |
| Exposure time | 48 h |
| Test substance | Water Accommodated Fraction |
| Remarks        | Based on data from similar materials |

| Toxicity to algae/aquatic plants | NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l |
| Exposure time | 72 h |
| Test substance | Water Accommodated Fraction |
| Method         | OECD Test Guideline 201 |
| Remarks        | Based on data from similar materials |

| Toxicity to daphnia and other aquatic invertebrates (Chron- | NOEC (Daphnia magna (Water flea)): 10 mg/l |
| Exposure time | 21 d |
Sulfapyridine Formulation

**SAFETY DATA SHEET**

**Test substance:** Water Accommodated Fraction
**Remarks:** Based on data from similar materials

**Sulfapyridine:**
**Toxicity to algae/aquatic plants:**
- EC10 (Raphidocelis subcapitata (freshwater green alga)): 1.0 mg/l
- End point: Growth rate
- Exposure time: 72 h

**Persistence and degradability**

**Components:**

**Petrolatum:**
**Biodegradability:**
- Result: Not readily biodegradable.
- Biodegradation: 31%
- Exposure time: 28 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

**Bioaccumulative potential**
No data available

**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 2811
- **Proper shipping name:** TOXIC SOLID, ORGANIC, N.O.S. (Sulfapyridine)

- **Class:** 6.1
- **Packing group:** III
- **Labels:** 6.1

**IATA-DGR**
- **UN/ID No.:** UN 2811
- **Proper shipping name:** Toxic solid, organic, n.o.s. (Sulfapyridine)
Class: 6.1
Packing group: III
Labels: Toxic
Packing instruction (cargo aircraft): 677
Packing instruction (passenger aircraft): 670

IMDG-Code
UN number: UN 2811
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Sulfapyridine)

Class: 6.1
Packing group: III
Labels: 6.1
EmS Code: F-A, S-A
Marine pollutant: no

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

Domestic regulation
NOM-002-SCT
UN number: UN 2811
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Sulfapyridine)

Class: 6.1
Packing group: III
Labels: 6.1

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
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

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SECTION 16. OTHER INFORMATION

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value


Revision Date: 09.09.2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8