SECTION 1. IDENTIFICATION

Product name: Phthalylsulfathiazole / Sulfamerazine 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
Not a hazardous substance or mixture.

GHS label elements
No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

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 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>Kaolin</td>
<td>Hydrated aluminum silicate</td>
<td>1332-58-7</td>
<td>75</td>
</tr>
<tr>
<td>Aluminum hydroxide</td>
<td>No data available</td>
<td>21645-51-2</td>
<td>10</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>Benzenesulfonamide, 4-amino-</td>
<td>127-79-7</td>
<td>5</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 if symptoms occur.

In case of skin contact
Wash with water and soap. Get medical attention if symptoms occur.

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. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders
No special precautions are necessary for first aid responders.

Notes to physician
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

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
Nitrogen oxides (NOx)
Sulfur oxides
Metal oxides
Silicon 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
Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
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:
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:
Use only with adequate ventilation.

Advice on safe handling:
Do not breathe dust.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
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.

Conditions for safe storage:
Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents
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>Kaolin</td>
<td>1332-58-7</td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>2 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Phthalylsulfathiazole</td>
<td>85-73-4</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>TWA (Respirable)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>127-79-7</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m³)</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 face shield 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 degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: fine powder
Color: White to light yellow
Odor: characteristic
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 explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): Not applicable
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: practically insoluble

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 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.

Components:

Kaolin:
  Acute oral toxicity:
    LD50 (Rat): > 5,000 mg/kg
    Remarks: Based on data from similar materials
Acute inhalation toxicity: LC50 (Rat): > 2.07 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Assessment: The substance or mixture has no acute inhalation toxicity
   Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 5,000 mg/kg
   Assessment: The substance or mixture has no acute dermal toxicity
   Remarks: Based on data from similar materials

Phthalylsulfathiazole:
Acute oral toxicity: LD50 (Rat, female): > 2,000 mg/kg
   Method: OECD Test Guideline 423
   Assessment: The substance or mixture has no acute oral 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

Aluminum hydroxide:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 423
   Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity: LC50 (Rat): > 5.09 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Assessment: The substance or mixture has no acute inhalation toxicity
   Remarks: Based on data from similar materials

Sulfamerazine:
Acute oral toxicity: LD50 (Mouse): 25,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Kaolin:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials
Phthalylsulfathiazole / Sulfamerazine Formulation

Version: 2.1  Revision Date: 09/30/2023  SDS Number: 5939788-00008  Date of last issue: 04/04/2023  Date of first issue: 05/26/2020

Phthalylsulfathiazole:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Aluminum hydroxide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Kaolin:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Phthalylsulfathiazole:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Aluminum hydroxide:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:
Aluminum hydroxide:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Aluminum hydroxide:**

Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Result: positive
  - Remarks: Based on data from similar materials
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: equivocal
  - Remarks: Based on data from similar materials
- Test Type: in vitro micronucleus test
  - Result: positive
  - Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Aluminum hydroxide:**

Species: Rat
Application Route: Inhalation (dust/mist/fume)
Exposure time: 86 weeks
Result: negative
Remarks: Based on data from similar materials

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**Aluminum hydroxide:**

Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.1 Revision Date: 09/30/2023 SDS Number: 5939788-00008 Date of last issue: 04/04/2023
Date of first issue: 05/26/2020

Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Aluminum hydroxide:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 364 Days
Method: OECD Test Guideline 426
Remarks: Based on data from similar materials

Species: Rat
NOAEL: > 0.2 mg/kg
Application Route: inhalation (dust/mist/fume)
Exposure time: 12 Months
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Kaolin:
Toxicity to fish (Chronic toxicity): NOELR (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 30 d

Phthalylsulfathiazole:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

**Aluminum hydroxide:**
Toxicity to fish: LL50 (Salmo trutta (brown trout)): > 100 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants: EL50 (Selenastrum capricornutum (green algae)): > 100 mg/l
Exposure time: 96 h

**Sulfamerazine:**
Toxicity to fish: LC50 (Morone saxatilis (striped bass)): > 100 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 227 mg/l
Exposure time: 48 h

**Persistence and degradability**
No data available

**Bioaccumulative potential**

**Components:**

**Phthalylsulfathiazole:**
Partition coefficient: n-octanol/water: log Pow: -2

**Sulfamerazine:**
Partition coefficient: n-octanol/water: log Pow: 0.728

**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.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWA EV : 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
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.