1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Silver Sulfadiazine Cream (Greenstone LLC)
Trade Name: Not established
Chemical Family: Sulfonamide

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antimicrobial

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>White petrolatum</td>
<td>8009-03-8</td>
<td>232-373-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>204-017-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:  Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:  Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:  Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:  Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:  No data available

Medical Conditions Aggravated by Exposure:  None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:  None

5. FIRE FIGHTING MEASURES

Extinguishing Media:  Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:  Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:  Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting:
Collect the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
- Storage Conditions: Store as directed by product packaging.
- Specific end use(s): Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Silver sulfadiazine
Manufacturer OEL: 2000ug/m³

Propylene glycol
Australia TWA 150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs
150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA
7 mg/m³

Lithuania OEL - TWA
7 mg/m³

White petrolatum
ACGIH Threshold Limit Value (TWA) 5 mg/m³ (oil mist, mineral)
ACGIH Threshold Limit Value (STEL) 10 mg/m³ (oil mist, mineral)

Stearyl Alcohol
Germany - TRGS 900 - TWAs 20 ppm
224 mg/m³

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Personal Protective Equipment: Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Cream</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flammability:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Hazardous Decomposition Products:
No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Contact with sulfonamides may cause dermatitis. Allergic skin reaction may occur based on effects of other sulfonamides. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria.

Acute Toxicity: (Species, Route, End Point, Dose)

Silver sulfadiazine
Rat  Oral  LD50  > 10 g/kg

Isopropyl myristate
Mouse  Oral  LD50  49,700 mg/kg
Rabbit  Dermal  LD50  5000 mg/kg

PEG-40 Stearate
Rat  Oral  LD50  > 20,000 mg/kg

Propylene glycol
Rat  Oral  LD50  22,000 mg/kg
Mouse  Oral  LD 50  24,900 mg/kg
Rabbit  Dermal  LD 50  20,800 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Propylene glycol
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

Stearyl Alcohol
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Silver sulfadiazine
Embryo / Fetal Development  Rabbit  Oral  Dose not specified  NOAEL  Not teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
11. TOXICOLOGICAL INFORMATION

Silver sulfadiazine
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Silver sulfadiazine
24 Month(s)  Rat  Dermal  NOAEL  Not carcinogenic
18 Month(s)  Mouse  Dermal  NOAEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been investigated.
Toxicity:  No data available
Persistence and Degradability:  No data available
Bio-accumulative Potential:  No data available
Mobility in Soil:  No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
None required

Methylparaben
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Silver sulfadiazine
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List 244-834-5

Sorbitan monoooleate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 215-665-4

Isopropyl myristate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 203-751-4

Propylene glycol
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 244-834-5

PEG-40 Stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed
15. REGULATORY INFORMATION

White petrolatum
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Carcinogens Category 2: Present
- EU EINECS/ELINCS List: 232-373-2

Stearyl Alcohol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 204-017-6

Water, purified
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

Additional Information: White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

16. OTHER INFORMATION

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 07-Nov-2017

Prepared by: Product Stewardship Hazard Communication

Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet