



# SAFETY DATA SHEET

Revision date: 07-Nov-2017

Version: 1.0

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## 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

### Details of the Supplier of the Safety Data Sheet

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300

## 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	*
White petrolatum	8009-03-8	232-373-2	Not Listed	*
Stearyl Alcohol	112-92-5	204-017-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*

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Silver sulfadiazine	22199-08-2	244-834-5	Not Listed	1
Sorbitan monooleate	1338-43-8	215-665-4	Not Listed	*
Isopropyl myristate	110-27-0	203-751-4	Not Listed	*
PEG-40 Stearate	9004-99-3	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### 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

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<b>Measures for Cleaning / Collecting:</b>	Contain 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.
<b>Additional Consideration for Large Spills:</b>	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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Silver sulfadiazine

Manufacturer OEL: 2000ug/m<sup>3</sup>

#### Propylene glycol

Australia TWA 150 ppm  
474 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>

Ireland OEL - TWAs 150 ppm  
470 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>

Latvia OEL - TWA 7 mg/m<sup>3</sup>  
Lithuania OEL - TWA 7 mg/m<sup>3</sup>

#### White petrolatum

ACGIH Threshold Limit Value (TWA) 5 mg/m<sup>3</sup> (oil mist, mineral)  
ACGIH Threshold Limit Value (STEL) 10 mg/m<sup>3</sup> (oil mist, mineral)

#### Stearyl Alcohol

Germany - TRGS 900 - TWAs 20 ppm  
224 mg/m<sup>3</sup>

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

##### Personal Protective Equipment:

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.

##### 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.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Cream	<b>Color:</b>	White to off-white
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Silver sulfadiazine**

No data available

**Water, purified**

No data available

**Methylparaben**

No data available

**Isopropyl myristate**

No data available

**Sorbitan monooleate**

No data available

**PEG-40 Stearate**

No data available

**Propylene glycol**

No data available

**White petrolatum**

No data available

**Stearyl Alcohol**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

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### 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 LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900mg/kg

Rabbit Dermal LD 50 20,800mg/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)

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### 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

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### 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:	Schedule 4
EU EINECS/ELINCS List	244-834-5

#### **Sorbitan monooleate**

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	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	200-338-0

#### **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



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### 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 - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
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  
Product Stewardship Hazard Communication

#### Prepared by:

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**