



# SAFETY DATA SHEET

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

### Product Identifier

**Material Name: Mesalamine Suppositories (Greenstone LLC)**

**Trade Name:** Not established

**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product

### 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

Skin Corrosion/Irritation: Category 2

Serious Eye Damage/Eye Irritation: Category 2A

Skin Sensitization: Category 1

Specific target organ systemic toxicity (single exposure): Category 3

### Label Elements

**Signal Word:** Warning

**Hazard Statements:**  
H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation

**Precautionary Statements:**  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P264 - Wash hands thoroughly after handling  
P271 - Use only outdoors or in a well-ventilated area  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P362 - Take off contaminated clothing and wash before reuse  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards Note:**

No data available

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  | %          |
|------------|------------|-----------------------|---|------------|
| Mesalamine | 89-57-6    | 201-919-1             | Skin Irrit 2 (H315)<br>Eye Irrit 2 (H319)<br>Skin Sens 1 (H317)<br>STOT SE 3 (H335) | 1000 mg*** |

| Ingredient | CAS Number   | EU EINECS/ELINCS List | GHS Classification | % |
|------------|--------------|-----------------------|--------------------|---|
| Hard fat   | Not assigned | Not Listed            | Not Listed         | * |

**Additional Information:**

\*\*\* per tablet/capsule/lozenge/suppository  
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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 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:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions:** None known

**Aggravated by Exposure:**

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### 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. May include oxides of carbon and nitrogen.

**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:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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. Store in cool place out of sun and away from heat.

**Storage Temperature:** Store below 25°C

**Specific end use(s):** Pharmaceutical product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

No exposure limits established.

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

##### 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 disposable gloves (e.g. Nitrile, etc.) (double 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 goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Solid Suppository

#### Color:

Light tan to gray

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

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

#### Hard fat

No data available

#### Mesalamine

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

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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  
Hazardous Decomposition Products: No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

General Information: The following information is available for the individual ingredients.  
Short Term: May cause allergic reaction in sensitive individuals, May cause eye and skin irritation (based on components) .  
Known Clinical Effects: Clinical use of this drug has caused dizziness, fever, skin rash, acne, headache, nausea, diarrhea.

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

##### Mesalamine

Rat Oral LD50 2800 mg/kg

Rabbit Dermal LD50 > 5000mg/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)

##### Mesalamine

Eye Irritation Rabbit Irritant

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

##### Mesalamine

Reproductive & Fertility Rat Oral 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus  
Embryo / Fetal Development Rabbit Oral Dose not specified Not Teratogenic

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Mesalamine

Bacterial Mutagenicity (Ames) Negative  
Mouse Lymphoma Assay Negative  
Micronucleus Mouse Negative

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

##### Mesalamine

2 Year(s) Rat Oral 320 mg/kg/day NOAEL Not carcinogenic

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### 11. TOXICOLOGICAL INFORMATION

**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. Releases to the environment should be avoided.

**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

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

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### 15. REGULATORY INFORMATION

#### Mesalamine

|  |            |
|--|------------|
| CERCLA/SARA 313 Emission reporting                         | Not Listed |
| California Proposition 65                                  | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                | Present    |
| Australia (AICS):  | Present    |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List                                      | 201-919-1  |

#### Hard fat

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| EU EINECS/ELINCS List              | Not Listed |

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

|                              |   |
|------------------------------|---|
| <b>Data Sources:</b>         | Publicly available toxicity information.  |
| <b>Reasons for Revision:</b> | Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.<br>Updated Section 16 - Other Information. |
| <b>Revision date:</b>        | 27-Aug-2018<br>Product Stewardship Hazard Communication   |
| <b>Prepared by:</b>          | 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**