# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Colestipol Hydrochloride for Oral Suspension (Greenstone LLC)**

**Trade Name:** Not applicable
**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product for the treatment of high cholesterol (hyperlipidemia)

**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**

**Signal Word:** Not required
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

**Other Hazards** No data available
**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 | % |
|---|---|---|---|---|
| Silicon dioxide, NF | 7631-86-9 | 231-545-4 | Not Listed | * |
| Colestipol Hydrochloride | 37296-80-3 | Not Listed | Not Listed | 5 gm |

**Additional Information:** * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 4. FIRST AID MEASURES

**Description of First Aid Measures**

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**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 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 fire fighting 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. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

## 7. HANDLING AND STORAGE

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. Wash hands and any exposed skin after removal of PPE. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.**

**Silicon dioxide, NF**

| | |
|---|---|
| **Australia TWA** | 2 mg/m$^3$ |
| **Austria OEL - MAKs** | 4 mg/m$^3$<br>0.3 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 0.1 mg/m$^3$<br>4.0 mg/m$^3$ |
| **Estonia OEL - TWA** | 2 mg/m$^3$ |
| **Finland OEL - TWA** | 5 mg/m$^3$ |
| **Germany - TRGS 900 - TWAs** | 4 mg/m$^3$ |
| **Germany (DFG) - MAK** | 4 mg/m$^3$ |
| **Ireland OEL - TWAs** | 6 mg/m$^3$<br>2.4 mg/m$^3$ |
| **Latvia OEL - TWA** | 1 mg/m$^3$ |
| **OSHA - Final PELs - Table Z-3 Mineral D:** | 20 mppcf<br>Listed |
| **Slovakia OEL - TWA** | 4.0 mg/m$^3$ |

**Colestipol Hydrochloride**

| | |
|---|---|
| **Manufacturer OEL:** | 3000ug/m$^3$ |

**Exposure Controls**

**Engineering Controls:** General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. 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).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Physical State:** | Granules | **Color:** | Light yellow |
| **Odor:** | Odorless | **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)**
**Silicon dioxide, NF**
No data available
**Colestipol Hydrochloride**
Predicted Log P -1.32
**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

**Flammablity:**
- **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
- **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:** Not acutely toxic (based on components) .
**Long Term:** Animal studies indicate that this material may cause adverse effects on the endocrine system.
**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include gastrointestinal disturbances, flatulence, vomiting, nausea, diarrhea, abdominal pain, constipation, dizziness, and headache.

## 11. TOXICOLOGICAL INFORMATION

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

**Colestipol Hydrochloride**
Rat Oral LD50 >1000 mg/kg
Mouse Oral LD50 >1000 mg/kg
Rat Intraperitoneal LD50 >4000 mg/kg
Mouse Intraperitoneal LD50 >4000 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)**

**Colestipol Hydrochloride**
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Non-irritating

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Colestipol Hydrochloride**
1 Month(s) Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose
14 Day(s) Rabbit Oral 4000 mg/kg/day NOAEL No effects at maximum dose
1 Month(s) Dog Oral 3000 mg/kg/day LOAEL None identified
18 Month(s) Rat Oral 2000 mg/kg/day NOAEL No effects at maximum dose
1 Year(s) Dog Oral 500 mg/kg/day LOAEL None identified

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Colestipol Hydrochloride**
Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 1000 mg/kg/day NOAEL Not Teratogenic

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

**Colestipol Hydrochloride**
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

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

**Colestipol Hydrochloride**
18 Month(s) Rat Oral 2000 mg/kg/day 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 thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Colestipol Hydrochloride**
Predicted Log P -1.32

**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
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**Silicon dioxide, NF**

| | |
|---|---|
| **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** | 231-545-4 |

## 15. REGULATORY INFORMATION

**Colestipol Hydrochloride**

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

## 16. OTHER INFORMATION

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date:** 05-Jan-2016

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**