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

Product Identifier

Material Name: Sildenafil Citrate Tablets (Greenstone LLC)

Trade Name: Not applicable
Synonyms: Sildenafil citrate tablets
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used for male erectile dysfunction

Details of the Supplier of the Safety Data Sheet

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Serious Eye Damage/Eye Irritation: Category 2B

EU Classification:
EU Indication of danger: Not classified

Label Elements

Signal Word: Warning
Hazard Statements: H320 - Causes eye irritation

Precautionary Statements: P264 - Wash hands thoroughly after handling
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

Other Hazards

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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
### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sildenafil citrate</td>
<td>171599-83-0</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>Acute Tox.4 (H302) Eye Irrit.2B (H320) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)</td>
<td>23</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 2, Aluminum lake</td>
<td>16521-38-3</td>
<td>240-589-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Triacetin</td>
<td>102-76-1</td>
<td>203-051-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.

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 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: 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
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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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.

### Sildenafil citrate

Manufacturer OEL: 350ug/m³

### Titanium dioxide

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **ACGIH OELs - Notice of Intended Changes**: Listed
- **Australia TWA**: 10 mg/m³
- **Austria OEL - MAKs**: 5 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Denmark OEL - TWA**: 6 mg/m³
- **Estonia OEL - TWA**: 5 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Iceland OEL - TWAs**: 5 mg/m³
- **Ireland OEL - TWA**: 10 mg/m³
- **Latvia OEL - TWA**: 10 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Poland OEL - TWA**: 10.0 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³

### Calcium phosphate dibasic, anhydrous

- **Latvia OEL - TWA**: 10 mg/m³

### Microcrystalline cellulose

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Estonia OEL - TWA**: 10 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 4 mg/m³
- **Latvia OEL - TWA**: 2 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³

### Magnesium stearate

- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³
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. Keep airborne contamination levels below the exposure limits listed above in this section.

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Blue or White</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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) Predicted 7.4 Log D 2.26
Calcium phosphate dibasic, anhydrous
No data available
Microcrystalline cellulose
No data available
Magnesium stearate
No data available
Crocarmellose sodium
No data available
Sildenafil citrate Predicted
Hydroxypropyl methylcellulose
No data available
Titanium dioxide
No data available
Lactose Monohydrate
No data available
Triacetin
No data available
FD & C Blue No. 2, Aluminum lake
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
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: Active ingredient may be harmful if swallowed. May cause eye irritation (based on components).

Long Term: Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

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

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Sildenafil citrate
- Rat Oral LDmin. 300-500 mg/kg
- Mouse Oral LDmin. 500-1000 mg/kg
- Rat Dermal LD50 > 2000 mg/kg

Hydroxypropyl methylcellulose
- Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg
11. TOXICOLOGICAL INFORMATION

Lactose Monohydrate
Rat  Oral  LD 50  29700 mg/kg

Triacetin
Rat  Oral  LD 50  3000 mg/kg
Mouse  Oral  LD 50  1100 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)

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

Sildenafil citrate
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Non-irritating
Skin Sensitization  Guinea Pig  Negative

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

Sildenafil citrate
6 Month(s)  Rat  Oral  3 mg/kg/day  NOAEL  Adrenal gland, Liver, Thyroid
6 Month(s)  Dog  Oral  15 mg/kg/day  NOAEL  Cardiovascular system

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

Sildenafil citrate
Reproductive & Fertility  Rat  Oral  60 mg/kg/day  NOEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Oral  50 mg/kg/day  NOEL  Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  50 mg/kg/day  NOEL  Maternal Toxicity, Not Teratogenic

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

Sildenafil citrate
In Vitro  Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro  Cytogenetics  Human Lymphocytes  Negative
In Vivo  Micronucleus Chromosome Aberration  Mouse Bone Marrow  Negative

Lactose Monohydrate
In Vitro  Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative

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

Sildenafil citrate
24 Month(s)  Mouse  Oral  5 mg/kg/day  NOAEL  Not carcinogenic
24 Month(s)  Rat  Oral  60 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.
11. TOXICOLOGICAL INFORMATION

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

- Sildenafil citrate
  - *Daphnia magna* (Water Flea) TAD EC50 48 Hours 14 mg/L
  - *Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L
  - *Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 Hours 20 mg/L

Aquatic Toxicity Comments: A greater than (> ) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

- Sildenafil citrate
  - Activated sludge OECD EC50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Sildenafil citrate

Predicted 7.4 Log D 2.26

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.

**FD & C Blue No. 2, Aluminum lake**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>240-589-3</td>
</tr>
</tbody>
</table>

**Lactose Monohydrate**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Triacetin**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>203-051-9</td>
</tr>
</tbody>
</table>

**Hydroxypropyl methylcellulose**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Croscarmellose sodium**

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

EU EINECS/ELINCS List: Not Listed

Sildenafil citrate
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  EU EINECS/ELINCS List: Not Listed

Titanium dioxide
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b):
    Australia (AICS): Present
    EU EINECS/ELINCS List: 236-675-5

Calcium phosphate dibasic, anhydrous
  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: 231-826-1

Microcrystalline cellulose
  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 9[f]. powder
  EU EINECS/ELINCS List: 232-674-9

Magnesium 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: 209-150-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Serious eye damage/eye irritation-Cat. 2B; H320 - Causes eye irritation
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful

R22 - Harmful if swallowed.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
Reasons for Revision:  
Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 23-Sep-2015
Prepared by: 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