



# SAFETY DATA SHEET

Revision date: 20-Jun-2017

Version: 2.2

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## 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

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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2B

### 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

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 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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Sildenafil citrate	171599-83-0	Not Listed	Acute Tox.4 (H302) Eye Irrit.2B (H320) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	23
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
FD & C Blue No. 2, Aluminum lake	16521-38-3	240-589-3	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	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.

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**

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**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.

**Additional Information:** Not applicable

## 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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Sildenafil citrate

Manufacturer OEL: 350ug/m<sup>3</sup>

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Austria OEL - MAKs 5 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
Denmark OEL - TWA 6 mg/m<sup>3</sup>  
Estonia OEL - TWA 5 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 5 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 4 mg/m<sup>3</sup>  
Latvia OEL - TWA 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Poland OEL - TWA 10.0 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 mg/m<sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Estonia OEL - TWA 10 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 4 mg/m<sup>3</sup>  
Latvia OEL - TWA 2 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Exposure Controls

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<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Blue or 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.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Calcium phosphate dibasic, anhydrous</b>	No data available		
<b>Microcrystalline cellulose</b>	No data available		
<b>Magnesium stearate</b>	No data available		
<b>Croscarmellose sodium</b>	No data available		
<b>Sildenafil citrate</b>	Predicted 7.4 Log D 2.26		
<b>Hydroxypropyl methylcellulose</b>	No data available		
<b>Lactose Monohydrate</b>	No data available		
<b>Triacetin</b>	No data available		
<b>FD &amp; C Blue No. 2, Aluminum lake</b>	No data available		
<b>Titanium dioxide</b>	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

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  
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/m<sup>3</sup>

##### Sildenafil citrate

Rat Oral LDmin. 300-500 mg/kg  
Mouse Oral LDmin. 500-1000 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Dermal LD50 > 2000 mg/kg

#### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

#### Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

#### Triacetin

Rat Oral LD 50 3000 mg/kg

Mouse Oral LD 50 1100mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 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 NOEL Adrenal gland, Liver, Thyroid

6 Month(s) Dog Oral 15 mg/kg/day NOEL 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

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### 11. TOXICOLOGICAL INFORMATION

#### 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 present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

#### 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

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

##### Sildenafil citrate

Predicted 7.4 Log D 2.26

#### Mobility in Soil:

No data available



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### 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**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	240-589-3

#### **Lactose Monohydrate**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed

#### **Triacetin**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	203-051-9

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### 15. REGULATORY INFORMATION

#### Hydroxypropyl methylcellulose

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	Not Listed

#### Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
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	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
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
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

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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

**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 8 - Exposure Controls / Personal Protection. Updated Section 2 - Hazard Identification. Updated Section 12 - Ecological Information.

**Revision date:** 20-Jun-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**