

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

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

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:  
800-435-7095

**Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)**

Trade Name:	Not applicable
Synonyms:	None
Chemical Family:	Selective serotonin re-uptake inhibitor (SSRI)
Intended Use:	Pharmaceutical product used as, antidepressant

**2. HAZARDS IDENTIFICATION**

Appearance: Light green, Light blue, or Light yellow film-coated tablets  
Signal Word: CAUTION

Statement of Hazard: Harmful if swallowed.  
Very toxic to aquatic life.

**Additional Hazard Information:**

Short Term: An Occupational Exposure Value (Limits, Bands, etc.) has been established for one or more of the ingredients (see Section 8).

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, diarrhea, insomnia, and headache. Signs and symptoms associated with non-fatal overdosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

EU Indication of danger: Harmful  
Dangerous for the Environment

**EU Hazard Symbols:**

Xn

N

**EU Risk Phrases:**

R22 - Harmful if swallowed.

R50 - Very toxic to aquatic organisms.

Hazardous Substance. Dangerous Goods.

**Australian Hazard Classification (NOHSC):****Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

# MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)  
Revision date: 13-Jun-2011

Page 2 of 8

Version: 2.1

## 2. HAZARDS IDENTIFICATION

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Sertraline hydrochloride	79559-97-0	Not Listed	N;R50 Xn;R22	37
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*

### Additional Information:

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

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. 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.
- 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.

## 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Not determined

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)  
Revision date: 13-Jun-2011

Page 3 of 8

Version: 2.1

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of the spill or leak. Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	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 hands and any exposed skin after removal of PPE. 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. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.
<b>Storage Conditions:</b>	Store as directed by product packaging.

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)

Page 4 of 8

Revision date: 13-Jun-2011

Version: 2.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### 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>
	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>

#### Sertraline hydrochloride

Manufacturer OEL:	500ug/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>

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

#### Analytical Method:

An analytical method may be available for the compound(s) listed above (Contact Greenstone for additional details)

#### 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

Physical State:	Tablet	Color:	Light blue, Light green or Light yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Partition Coefficient (Calculated; pH 7.4 - Log D):	2.39 (pH 7) (Sertraline HCl)		

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)

Page 5 of 8

Revision date: 13-Jun-2011

Version: 2.1

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Polymerization: Will not occur

Partition Coefficient (n-octanol/water - Log P): 2.9 (pH 7) (Sertraline HCl)

### 10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.  
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.  
Incompatible Materials: Strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

#### 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>

##### Sertraline hydrochloride

Mouse Oral LD50 419 - 548 mg/kg  
Rat Oral LD50 1327 - 1591 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

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

##### Sertraline hydrochloride

3 Month(s)	Rat	Oral	80 mg/kg/day	LOAEL	Liver
3 Month(s)	Dog	Oral	80 mg/kg/day	LOAEL	Liver
1 Year(s)	Dog	Oral	30 mg/kg/day	LOAEL	Central Nervous System
2 Year(s)	Rat	Oral	40 mg/kg/day	LOAEL	Liver

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

##### Sertraline hydrochloride

Peri-/Postnatal Development	Rat	Oral	20 mg/kg/day	LOAEL	Early embryonic development, Developmental toxicity
Reproductive & Fertility	Rat	Oral	80 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility	Rat	Oral	10 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral	40 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	80 mg/kg/day	NOAEL	Not Teratogenic

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)  
Revision date: 13-Jun-2011

Page 6 of 8

Version: 2.1

### 11. TOXICOLOGICAL INFORMATION

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

##### Sertraline hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Bone Marrow Metaphase Analysis	Mouse	Negative
<i>In Vitro</i> Cytogenetics	Mouse Bone Marrow	Negative

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

##### Sertraline hydrochloride

2 Year(s)	Rat	Oral	40 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	40 mg/kg/day	LOAEL	Benign tumors, Liver, Lungs

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

The environmental characteristics of this mixture have not been fully evaluated. In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

#### Mobility, Persistence and Degradability:

The active ingredient in this formulation is water soluble and is expected to remain primarily in water.

#### Bioaccumulation and Toxicity:

High acute toxicity to aquatic organisms is expected. Toxicity to wastewater treatment microorganisms may occur. See aquatic toxicity data, below.

##### Partition Coefficient

(Calculated; pH 7.4 - Log D):

##### Partition Coefficient

(n-octanol/water - Log P):

##### Calculated BCF:

2.39 (pH 7) (Sertraline HCl)

2.9 (pH 7) (Sertraline HCl)

10.4 (Sertraline HCl)

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

##### Sertraline hydrochloride

<i>Daphnia magna</i> (Water Flea)	EC50	1.25 Hours	2.14 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	TAD LC50	96 Hours	0.30 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	NPDES EC50	96 Hours	0.03 mg/L
<i>Skeletonema costatum</i> (Marine Diatom)	NPDES EC50	96 Hours	0.03 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	TAD NOEC	12 Days	0.033 mg/L

### 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)

Page 7 of 8

Revision date: 13-Jun-2011

Version: 2.1

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

**UN number:** UN 3077  
**UN proper shipping name:** Environmentally Hazardous Substance, Solid, n.o.s (substituted naphthalenamine, hydrochloride salt)  
**Transport hazard class(es):** 9  
**Packing group:** III  
**Environmental Hazard(s):** Marine Pollutant

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Harmful  
Dangerous for the Environment

**EU Risk Phrases:**  
R22 - Harmful if swallowed.  
R50 - Very toxic to aquatic organisms.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S57 - Use appropriate containment to avoid environmental contamination.

**OSHA Label:**  
CAUTION  
Harmful if swallowed.  
Very toxic to aquatic life.

#### 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.

**Hydroxypropyl cellulose**

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

**Dibasic calcium phosphate, dihydrate USP**

Australia (AICS): Present

## MATERIAL SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Tablets (Greenstone LLC)

Page 8 of 8

Revision date: 13-Jun-2011

Version: 2.1

### 15. REGULATORY INFORMATION

#### Sodium starch glycolate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

#### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

#### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R50 - Very toxic to aquatic organisms.

#### 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 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 14 - Transport Information.

#### Prepared by:

Product Stewardship Hazard Communication  
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**