

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**Product Identifier****Material Name:** Sertraline Hydrochloride Oral Solution (Greenstone LLC)**Trade Name:** Not applicable**Synonyms:** Sertraline Hydrochloride Oral Concentrate**Chemical Family:** Selective serotonin re-uptake inhibitor (SSRI)**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against****Intended Use:** antidepressant**Details of the Supplier of the Safety Data Sheet**Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095**Emergency telephone number:**
800-435-7095**2. HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****GHS - Classification**

Flammable liquids- Category 3

Label Elements**Signal Word:** Warning**Hazard Statements:** H226 - Flammable liquid and vapor**Precautionary Statements:** P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/Bond container and receiving equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P370 + P378 - In case of fire: Use CO2, extinguishing powder, foam, or water for extinction
P403 + P235 - Store in a well-ventilated place. Keep cool
P501 - Dispose of contents/container in accordance with all local and national regulations

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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 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.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sertraline hydrochloride	79559-97-0	Not Listed	Acute Tox.4 (H302) STOT RE.2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	2.0
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	12.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Menthol, USP	89-78-1	201-939-0	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.

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Medical Conditions: None known
Aggravated by Exposure:

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: Flammable liquid and vapor

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 the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. 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

Keep away from heat. Use adequate ventilation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. 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.

Sertraline hydrochloride	
Manufacturer OEL:	500ug/m ³
Ethyl alcohol (ethanol)	
ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³
France OEL - TWA	1000 ppm
	1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m ³
Germany (DFG) - MAK	500 ppm
	960 mg/m ³
Greece OEL - TWA	1000 ppm
	1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm
	1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m ³
Slovakia OEL - TWA	500 ppm
	960 mg/m ³
Slovenia OEL - TWA	1000 ppm
	1900 mg/m ³
Sweden OEL - TWAs	500 ppm
	1000 mg/m ³
Glycerin, USP	
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³

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Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	200 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	10 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	10 mg/m ³
Denmark OEL - TWA	10 mg/m ³
Finland OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Germany - TRGS 900 - TWAs	10 mg/m ³
Germany (DFG) - MAK	10 mg/m ³ can occur as vapor and aerosol at the same time
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

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). 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 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.)

Eyes:

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.)

Skin:

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.)

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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless
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)

Sertraline hydrochloride

Predicted 7.0 Log D 2.39

Menthol, USP

No data available

Glycerin, USP

No data available

Ethyl alcohol (ethanol)

No data available

Butylated hydroxytoluene

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):	27
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

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

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

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11. TOXICOLOGICAL INFORMATION

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

Short Term: May be harmful if swallowed. May cause irritation (based on components) .

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.

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

Sertraline hydrochloride

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

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 > 21.9 g/kg

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060mg/kg
Rat Inhalation LC50 10h 20,000ppm

Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg
Mouse Oral LD50 650 mg/kg
Rat Oral LD50 890 mg/kg
Mouse Intraperitoneal LD 50 138 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)

Glycerin, USP

Eye Irritation Rabbit Mild

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Butylated hydroxytoluene

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

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11. TOXICOLOGICAL INFORMATION

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

Butylated hydroxytoluene

4 Week(s)	Rat	Oral	5185 mg/kg	LOAEL	Liver
4 Day(s)	Mouse	Oral	2000 mg/kg	LOAEL	Liver, Kidney, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, 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

Butylated hydroxytoluene

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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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:

Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

Ethyl alcohol (ethanol)

IARC: Group 1 (Carcinogenic to Humans)

Butylated hydroxytoluene

IARC: Group 3 (Not Classifiable)

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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. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

Toxicity:

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

Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	50 mg/L
<i>Daphnia magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L

Ethyl alcohol (ethanol)

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50/96h	12,900-15,300 mg/L
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Persistence and Degradability: No data available

Ethyl alcohol (ethanol) Not Ready

Bio-accumulative Potential:

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

Sertraline hydrochloride

Predicted 7.0 Log D 2.39

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.

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

UN number: UN 1170

PZ00449

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UN proper shipping name: Ethanol Solution
Transport hazard class(es): 3
Packing group: III
Flash Point (°C): 27
Flash Point (°C): 27

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

D2b toxic materials



Menthol, USP

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	201-939-0

Sertraline hydrochloride

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

Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Glycerin, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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15. REGULATORY INFORMATION

REACH - Annex V - Exemptions from the obligations of Register:

Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bio accumulative, and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern

EU EINECS/ELINCS List

200-289-5

Butylated hydroxytoluene

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

204-881-4

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic 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 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date:

26-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