



# SAFETY DATA SHEET

Revision date: 22-Apr-2015

Version: 3.1

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

### Product Identifier

**Material Name:** Sertraline Hydrochloride Oral Concentrate (Greenstone LLC)

**Trade Name:** Not applicable

**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

#### EU Classification:

EU Indication of danger: Flammable

EU Risk Phrases:

R10 - Flammable.

### 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** No data available  
**Australian Hazard Classification (NOHSC):** Hazardous Substance. Dangerous Goods.

**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	EU Classification	GHS Classification	%
Sertraline hydrochloride	79559-97-0	Not Listed	N;R50 Xn;R22	Acute Tox.4 (H302) STOT RE.2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	2.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	Not Listed	*
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	12.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Menthol, USP	89-78-1	201-939-0	Not Listed	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 R phrases and 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.

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**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:** 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.

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### 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<sup>3</sup>

#### Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA) 2 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Austria OEL - MAKs 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 2 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
Denmark OEL - TWA 10 mg/m<sup>3</sup>  
Finland OEL - TWA 10 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Germany - TRGS 900 - TWAs 10 mg/m<sup>3</sup>  
Germany (DFG) - MAK 10 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 2 mg/m<sup>3</sup>  
Slovenia OEL - TWA 10 mg/m<sup>3</sup>

#### Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL) 1000 ppm  
Australia TWA 1000 ppm  
1880 mg/m<sup>3</sup>  
Austria OEL - MAKs 1000 ppm  
1900 mg/m<sup>3</sup>  
Belgium OEL - TWA 1000 ppm  
1907 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 1000.0 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 1000 mg/m<sup>3</sup>  
Denmark OEL - TWA 1000 ppm  
1900 mg/m<sup>3</sup>  
Estonia OEL - TWA 500 ppm  
1000 mg/m<sup>3</sup>  
Finland OEL - TWA 1000 ppm  
1900 mg/m<sup>3</sup>  
France OEL - TWA 1000 ppm  
1900 mg/m<sup>3</sup>  
Germany - TRGS 900 - TWAs 500 ppm  
960 mg/m<sup>3</sup>  
Germany (DFG) - MAK 500 ppm  
960 mg/m<sup>3</sup>  
Greece OEL - TWA 1000 ppm  
1900 mg/m<sup>3</sup>  
Hungary OEL - TWA 1900 mg/m<sup>3</sup>  
Latvia OEL - TWA 1000 mg/m<sup>3</sup>  
Lithuania OEL - TWA 500 ppm  
1000 mg/m<sup>3</sup>  
Netherlands OEL - TWA 260 mg/m<sup>3</sup>

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OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m <sup>3</sup>
Poland OEL - TWA	1900 mg/m <sup>3</sup>
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Slovakia OEL - TWA	500 ppm 960 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Spain OEL - TWA	1000 ppm 1910 mg/m <sup>3</sup>
Sweden OEL - TWAs	500 ppm 1000 mg/m <sup>3</sup>

### Glycerin, USP

Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	50 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

### 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

#### 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

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	27
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

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

### 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:** 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.

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### 11. TOXICOLOGICAL INFORMATION

**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/m<sup>3</sup>

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

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

##### **Sertraline hydrochloride**

3 Month(s) Rat Oral 80 mg/kg/day LOAEL Liver



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### 11. TOXICOLOGICAL INFORMATION

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)	LD50	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

**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.

<b>UN number:</b>	UN 1170
<b>UN proper shipping name:</b>	Ethanol Solution
<b>Transport hazard class(es):</b>	3

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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

#### 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

#### Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 4/29/11 in alcoholic beverages developmental toxicity initial date 10/1/87 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
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
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, bioaccumulative, and toxic or very persistent and very bioaccumulative 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

### 16. OTHER INFORMATION

#### Text of R phrases and 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

Xn - Harmful  
F - Highly flammable  
N - Dangerous for the environment

R10 - Flammable.  
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 2 - Hazard Identification. Updated Section 14 - Transport Information.

**Revision date:** 22-Apr-2015

**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**