SAFETY DATA SHEET

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

Product Identifier

Material Name: Sertraline Hydrochloride Oral Concentrate - 20 mg/mL

Trade Name: ZOLOFT; TATIG; LUSTRAL; BESITRAN

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antidepressant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Flammable liquids- Category 3

EU Classification:
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
P241 - Use explosion-proof electrical/ventilating/lighting/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 .? 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
SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Oral Concentrate - 20 mg/mL
Revision date: 22-Aug-2014

Other Hazards
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.

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

<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>Menthol, USP</td>
<td>89-78-1</td>
<td>201-939-0</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 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.
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

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: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire / Explosion Hazards: Flammable liquid.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

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. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

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 spill with absorbent material. 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
SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Oral Concentrate - 20 mg/mL
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7. HANDLING AND STORAGE

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Ethyl alcohol (ethanol)

<table>
<thead>
<tr>
<th>Control Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>1000 ppm</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1880 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1907 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1000.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>960 mg/m³</td>
</tr>
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<td>Greece OEL - TWA</td>
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<td>1900 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>1900 mg/m³</td>
</tr>
</tbody>
</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russia OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>1000 ppm</td>
<td>1910 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Sertraline hydrochloride**

Pfizer OEL TWA-8 Hr: 500µg/m³

**Glycerin, USP**

- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Czech Republic OEL - TWA: 10 mg/m³
- Estonia OEL - TWA: 10 mg/m³
- Finland OEL - TWA: 20 mg/m³
- France OEL - TWA: 10 mg/m³
- Germany (DFG) - MAK: 50 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Poland OEL - TWA: 10 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL -TWAs: 50 mg/m³

**Butylated hydroxytoluene**

ACGIH Threshold Limit Value (TWA): 2 mg/m³

- Australia TWA: 10 mg/m³
- Austria OEL - MAKs: 10 mg/m³
- Belgium OEL - TWA: 2 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Denmark OEL - TWA: 10 mg/m³
- Finland OEL - TWA: 10 mg/m³
- France OEL - TWA: 10 mg/m³
- Germany - TRGS 900 - TWAs: 10 mg/m³
- Germany (DFG) - MAK: 10 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 10 mg/m³
- Switzerland OEL -TWAs: 10 mg/m³

**Exposure Controls**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:
- 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, colorless</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>2.9 (pH 7) (Sertraline HCl)</td>
</tr>
<tr>
<td>Menthol, USP</td>
<td>No data available</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>No data available</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>No data available</td>
</tr>
<tr>
<td>Butylated hydroxytoluene</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
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<tr>
<td>Vapor Pressure (kPa)</td>
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</tr>
<tr>
<td>Vapor Density (g/ml)</td>
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<tr>
<td>Relative Density</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Flammability:</td>
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</tr>
<tr>
<td>Autoignition Temperature (Solid)</td>
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<tr>
<td>Flammability (Solids)</td>
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<td>Flash Point (Liquid) (°C)</td>
<td>27</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water - Log P)</td>
<td>2.9 (pH 7) (Sertraline HCl)</td>
</tr>
</tbody>
</table>
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: Direct sunlight, excessive heat, sparks or open flame
   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.
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)
11. TOXICOLOGICAL INFORMATION

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
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

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

Sertraline hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
Bone Marrow Metaphase Analysis  Mouse  Negative
In Vitro 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
11. TOXICOLOGICAL INFORMATION

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)
OSHA: Listed

Butylated hydroxytoluene
IARC: Group 3 (Not Classifiable)

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
*Daphnia magna* (Water Flea) EC50 1.25 Hours 2.14 mg/L
*Pimephales promelas* (Fathead Minnow) TAD LC50 96 Hours 0.30 mg/L
*Pseudokirchneriella subcapitata* (Green Alga) NPDES EC50 96 Hours 0.03 mg/L
*Skeletonema costatum* (Marine Diatom) NPDES EC50 96 Hours 0.03 mg/L

Glycerin, USP
*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L
*Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

Ethyl alcohol (ethanol)
*Oncorhynchus mykiss* (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Aquatic Toxicity Comments:
A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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.

UN number: UN 1170
UN proper shipping name: Ethyl alcohol solution
Transport hazard class(es): 3
Packing group: III
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

Ethyl alcohol (ethanol)
CERCLA/SARA 313 Emission reporting: Not Listed
carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 in alcoholic beverages
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>REACH - Annex V - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sertraline hydrochloride</td>
<td>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</td>
<td>200-289-5</td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65</td>
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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

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

R50 - Very toxic to aquatic organisms.
R11 - Highly flammable.
R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Oral Concentrate - 20 mg/mL
Revision date: 22-Aug-2014

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information.

Revision date: 22-Aug-2014
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet