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

Product Identifier

Material Name: Sertraline Hydrochloride Capsules

Trade Name: ZOLOFT; ALTRULINE; LUSTRAL; TATIG

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute aquatic toxicity: Category 1
Chronic aquatic toxicity: Category 1

EU Classification:

EU Indication of danger: Dangerous for the Environment

EU Risk Phrases: R50 - Very toxic to aquatic organisms.

Label Elements

Signal Word: Warning
Hazard Statements: H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements: P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name:  Sertraline Hydrochloride Capsules
Revision date: 09-Mar-2015

Other Hazards
Australian Hazard Classification (NOHSC):

No data available
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

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 Chronic 1 (H410) 10-19
Sodium lauryl sulfate 151-21-3 205-788-1 Not Listed Not Listed *
Maize starch 9005-25-8 232-679-6 Not Listed Not Listed *
Magnesium stearate 557-04-0 209-150-3 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.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
**SAFETY DATA SHEET**

**Material Name:** Sertraline Hydrochloride Capsules

**Revision date:** 09-Mar-2015

**Version:** 2.0

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**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

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**5. FIRE FIGHTING MEASURES**

**Extinguishing Media:**
Use carbon dioxide, dry chemical, or water spray.

**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:**
Not determined

**Advice for Fire-Fighters**
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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**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.

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**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 hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

**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.

Sertraline hydrochloride
Pfizer OEL TWA-8 Hr: 500µg/m³

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Maize starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

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: Capsule
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available

Color: Dark green
Odor Threshold: No data available.
Molecular Weight: Mixture

PZ01753
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)

Mg stearate
No data available

Sertraline hydrochloride
Predicted 7.0 Log D 2.39

Lactose NF, anhydrous
No data available

Hard gelatin capsules
No data available

Sodium lauryl sulfate
No data available

Maize starch
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): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May be harmful if swallowed. (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the liver.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including suicidal behavior, 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)

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m³

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

Sodium lauryl sulfate
Rat  Oral  LD50  1288 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)

Sodium lauryl sulfate
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild Moderate
Skin Sensitization - GPMT  Guinea Pig  Negative
Skin Sensitization - LLNA  Mouse  Negative

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 & 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

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
11. TOXICOLOGICAL INFORMATION

In Vitro Cytogenetics  Mouse Bone Marrow  Negative

Sodium lauryl sulfate
Bacterial Mutagenicity (Ames)  Salmonella  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.

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
Pseudokirchneriella subcapitata (Green Alga)  TAD  NOEC  12 Days  0.033 mg/L

Sodium lauryl sulfate
Oncorhynchus mykiss (Rainbow Trout)  LC50  96 Hours  3.6 mg/L

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 transportation as a hazardous material/dangerous good.

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

5 kg/5L Exception: Effective January 1, 2015, UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:
* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

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.

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

Sodium lauryl sulfate
CERCLA/SARA 313 Emission reporting Not Listed
15. REGULATORY INFORMATION

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<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
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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
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

N - Dangerous for the environment
Xn - Harmful

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

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.
SAFETY DATA SHEET

Material Name: Sertraline Hydrochloride Capsules
Revision date: 09-Mar-2015

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 14 - Transport Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 09-Mar-2015
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without 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