MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Sertraline Hydrochloride Capsules

Trade Name: ZOLOFT; ALTRULINE; LUSTRAL; TATIG
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antidepressant

2. HAZARDS IDENTIFICATION

Appearance: Dark green hard gelatin capsules

Statement of Hazard: Very toxic to aquatic life.

Additional Hazard Information:
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 liver.

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.

EU Classification
EU Indication of danger: Dangerous for the Environment

EU Hazard Symbols:

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

Australian Hazard Classification (NOHSC): Hazardous Substance. Dangerous Goods.

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.

2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sertraline hydrochloride	79559-97-0	Not Listed	N;R50 Xn;R22	10-19
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Maize starch	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Hard gelatin capsules	MIXTURE	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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sertraline hydrochloride

Pfizer OEL TWA-8 Hr:	0.5 mg/m³

Magnesium stearate

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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	**Color:**	Dark green
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Partition Coefficient (Calculated; pH 7.4 - Log D): 2.39 (pH 7) (Sertraline HCl)

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: As a precautionary measure, keep away from 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)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Sertraline hydrochloride
Mouse Oral LD50 419 - 548 mg/kg

11. TOXICOLOGICAL INFORMATION

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
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.

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): 2.39 (pH 7) (Sertraline HCl)

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

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

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

15. REGULATORY INFORMATION

EU Symbol: N
EU Indication of danger: Dangerous for the Environment

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

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

OSHA Label:
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.

Magnesium stearate

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

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

Lactose NF, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

Maize starch

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

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

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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