



MATERIAL SAFETY DATA SHEET

Revision date: 04-Feb-2009

Version: 3.2

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

Product Identifier

Material Name: Sertraline hydrochloride tablets blend

Trade Name: ZOLOFT®
Synonyms: ZOLOFT® tablets blend
Chemical Family: Selective serotonin re-uptake inhibitor (SSRI)

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

Intended Use: Pharmaceutical blend: antidepressant

Details of the Supplier of the Safety Data Sheet

Pfizer Global Manufacturing
Pfizer Inc
235 East 42nd Street
New York, NY 10017

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:
ChemSafe (24 hours): +44 (0)208 762 8322

2. HAZARDS IDENTIFICATION

Appearance: White powder
Classification of the Substance or Mixture

EU Classification:

EU Indication of danger: Harmful
Dangerous for the Environment

EU Risk Phrases:

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

Label Elements

Other Hazards

No data available

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 overdose were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

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.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

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

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

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: 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: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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

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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.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing dust.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: 15 - 30 °C

Incompatible Materials: Oxidizers

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Analytical Method: Analytical method available for Sertraline hydrochloride. Contact Pfizer Inc for further information.

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Rubber gloves

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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:	Powder	Color:	White
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)
Hydroxypropyl cellulose
No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Dibasic calcium phosphate, dihydrate USP

No data available

Microcrystalline cellulose

No data available

Sodium starch glycolate

No data available

Magnesium stearate

No data available

Sertraline hydrochloride

Predicted 7.0 Log D 2.39

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: 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.

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/kg

Magnesium stearate

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11. TOXICOLOGICAL INFORMATION

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

Sertraline hydrochloride

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

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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 & Development Toxicity: (Duration, 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)	<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

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.

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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: No data available
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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available
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 when shipped in bulk (all modes) or non-bulk (water only).

IMDG IMDG

IMDG UN / ID No:	UN 3077
IMDG Proper shipping name:	Environmentally Hazardous Substance, solid, n.o.s. (substituted naphthalenamine, hydrochloride salt) Marine pollutant
IMDG Hazard Class:	9
IMDG Packing Group:	III

ADR/RID

ADR/RID Proper shipping name:	Environmentally Hazardous Substance, solid, n.o.s. (substituted naphthalenamine, hydrochloride salt)
ADR / RID Hazard Class:	9

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ADR / RID Packing Group: III
ADR / RID Item Number: UN 3077

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.

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R50 - Very toxic to aquatic organisms.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

Prepared by: Product Stewardship Hazard Communications
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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet