



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 3.1

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

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**Pfizer Pharmaceuticals Group**  
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CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Sertraline hydrochloride film coated tablets**

**Trade Name:** ZOLOFT(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antidepressant

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient                 | CAS Number | EU EINECS List | %  |
|----------------------------|------------|----------------|----|
| Sertraline hydrochloride   | 79559-97-0 | Not listed     | 37 |
| Microcrystalline cellulose | 9004-34-6  | 232-674-9      | *  |
| Magnesium stearate         | 557-04-0   | 209-150-3      | *  |

| Ingredient                               | CAS Number | EU EINECS List | % |
|------------------------------------------|------------|----------------|---|
| Hydroxypropyl cellulose                  | 9004-64-2  | Not listed     | * |
| Dibasic calcium phosphate, dihydrate USP | 7789-77-7  | Not listed     | * |
| Sodium starch glycolate                  | 9063-38-1  | Not listed     | * |

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Light green, Light blue, or Light yellow film-coated tablets  
**Signal Word:** WARNING

**Statement of Hazard:** May be harmful if swallowed.  
May cause liver and central nervous system effects  
Dangerous for the environment

### Additional Hazard Information:

**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.

**EU Indication of danger:** Harmful  
Dangerous for the Environment

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### EU Hazard Symbols:



### EU Risk Phrases:

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

**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.

## 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.

## 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.

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### 7. HANDLING AND STORAGE

**General Handling:** Use only in a well-ventilated area. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

**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 (59-86°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Sertraline hydrochloride**  
**Pfizer OEL TWA-8 Hr:** 0.5 mg/m<sup>3</sup>

**Microcrystalline cellulose**  
**OSHA - Final PELs - TWAs:** = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
**ACGIH Threshold Limit Value (TWA)** = 10 mg/m<sup>3</sup> TWA  
**Australia TWA** = 10 mg/m<sup>3</sup> TWA

**Magnesium stearate**  
**ACGIH Threshold Limit Value (TWA)** = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
**Australia TWA** = 10 mg/m<sup>3</sup> TWA  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

**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.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. 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:

|                                                            |                              |                          |                                          |
|------------------------------------------------------------|------------------------------|--------------------------|------------------------------------------|
| <b>Physical State:</b>                                     | Tablet                       | <b>Color:</b>            | Light green, Light blue, or Light yellow |
| <b>Molecular Formula:</b>                                  | Mixture                      | <b>Molecular Weight:</b> | Mixture                                  |
| <b>Partition Coefficient (Calculated; pH 7.4 - Log D):</b> | 2.39 (pH 7) (Sertraline HCl) |                          |                                          |
| <b>Partition Coefficient (n-octanol/water - Log P):</b>    | 2.9 (pH 7) (Sertraline HCl)  |                          |                                          |

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### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Not determined  
**Incompatible Materials:** Strong oxidizers  
**Polymerization:** Will not occur

### 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)

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Sertraline hydrochloride**

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

##### **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 & 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**

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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

**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** 2.39 (pH 7) (Sertraline HCl)

**(Calculated; pH 7.4 - Log D):**

**Partition Coefficient** 2.9 (pH 7) (Sertraline HCl)

**(n-octanol/water - Log P):**

**Calculated BCF:** 10.4 (Sertraline HCl)

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Sertraline hydrochloride

*Daphnia Magna* TAD EC50 48 Hours 0.56 mg/L  
Fathead minnow TAD LC50 96 Hours 0.30 mg/L  
Green algae TAD EC50 14 Days 0.056 mg/L  
Skeletonema Algae NPDES IC50 96 Hours 0.03 mg/L  
Green algae NPDES IC50 96 Hours 0.03 mg/L

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good when shipped in bulk (all modes) or non-bulk (water only).

IMDG

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**IMDG Proper shipping name:** Environmentally Hazardous Substance, solid, n.o.s. (substituted naphthalenamine, hydrochloride salt) Marine pollutant  
**IMDG UN / ID No:** UN 3077  
**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  
**ADR / RID Packing Group:** III  
**ADR / RID Item Number:** UN 3077

## 15. REGULATORY INFORMATION

**EU Symbol:** Xn , N  
**EU Indication of danger:** Harmful  
Dangerous for the Environment

**EU Risk Phrases:**  
R22 - Harmful if swallowed.  
R50 - Very toxic to aquatic organisms.

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

**OSHA Label:**  
WARNING  
May be harmful if swallowed.  
May cause liver and central nervous system effects  
Dangerous for the environment

### 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.

**Hydroxypropyl cellulose**  
**Inventory - United States TSCA - Sect. 8(b)** XU  
**Australia (AICS):** Present

**Dibasic calcium phosphate, dihydrate USP**  
**Australia (AICS):** Present

**Sodium starch glycolate**  
**Inventory - United States TSCA - Sect. 8(b)** XU  
**Australia (AICS):** Present

**Microcrystalline cellulose**  
**Inventory - United States TSCA - Sect. 8(b)** XU

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|                   |           |
|-------------------|-----------|
| Australia (AICS): | Present   |
| EU EINECS List    | 232-674-9 |

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

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.  
Updated Section 8 - Exposure Controls / Personal Protection.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**