



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 2.1

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

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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 Oral Concentrate - 20 mg/mL

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	2.0
Butylated hydroxytoluene, NF	128-37-0	204-881-4	*
Ethyl alcohol (ethanol)	64-17-5	200-578-6	12.0
Glycerin, USP	56-81-5	200-289-5	*

Ingredient	CAS Number	EU EINECS List	%
Menthol, USP	89-78-1	201-939-0	*

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid
Signal Word: WARNING

Statement of Hazard: Flammable liquid and vapor.
May be harmful if swallowed.
May cause eye irritation
May cause liver effects
May cause nervous system effects
Dangerous for the environment

Additional Hazard Information:

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.

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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.

EU Risk Phrases:

R10 - Flammable.
R52 - Harmful 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: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Fire / Explosion Hazards: Flammable liquid.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: 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.

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.

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

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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: 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.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a cool, well ventilated, dry area.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sertraline hydrochloride
Pfizer OEL TWA-8 Hr: 0.5 mg/m³

Butylated hydroxytoluene, NF
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Ethyl alcohol (ethanol)
OSHA - Final PELs - TWAs: = 1000 ppm TWA
= 1900 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
= 1880 mg/m³ TWA

Glycerin, USP
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: None required with normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid	Color:	Clear, colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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

Flash Point (Liquid) (°C): 27

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

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Direct sunlight, excessive heat, sparks or open flame
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)

Sertraline hydrochloride

Mouse Oral LD50 419 - 548 mg/kg
Rat Oral LD50 1327 - 1591 mg/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 7060 mg/kg
Rat Inhalation LC50 10h 20,000 ppm

Butylated hydroxytoluene, NF

Rat Oral LD50 890 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)

Glycerin, USP

Eye Irritation Rabbit Mild

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe

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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)	<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

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.

Butylated hydroxytoluene, NF

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:

The environmental characteristics of this material 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 environmental characteristics of this material have not been fully evaluated. 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 the aquatic toxicity data for the active ingredient in the table, below.

Partition Coefficient (Calculated; pH 7.4 - Log D):

2.39 at pH 7

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

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC-50 96 Hours 50 mg/L
Daphnia Magna (Water Flea) EC-50 24 Hours >500 mg/L

Ethyl alcohol (ethanol)

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.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

Proper shipping name: Ethyl alcohol solution
UN / ID No: UN 1170
Hazard class: 3
Packing group: III

Limited Quantity Exceptions may apply for small quantities packed in combination packaging. See applicable DOT/IATA/IMDG modal regulations for specific instructions. If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a consumer commodity and excepted from additional requirements as applicable. For domestic shipments, certain sizes may be subject to DOT-SP 9275; see DOT Special Permits for details.

IATA / ICAO

IATA Proper shipping name: Consumer Commodity
IATA UN / ID No: ID 8000
IATA Hazard Class: 9

IMDG

IMDG Proper shipping name: Ethyl alcohol solution, Ltd Qty
IMDG UN / ID No: UN 1170
IMDG Hazard Class: 3
IMDG Packing Group: III
IMDG additional info: Flash point 27 deg C

DOT

DOT Proper shipping name: Consumer Commodity
DOT Hazard Class: ORM-D

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15. REGULATORY INFORMATION

EU Symbol: None required

EU Risk Phrases:
R10 - Flammable.
R52 - Harmful to aquatic organisms.

EU Safety Phrases:
S16 - Keep away from sources of ignition - No smoking.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:

WARNING
Flammable liquid and vapor.
May be harmful if swallowed.
May cause eye irritation
May cause liver effects
May cause nervous system effects
Dangerous for the environment

Canada - WHMIS: Classifications

WHMIS hazard class:

D2b toxic materials



Butylated hydroxytoluene, NF

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 204-881-4

Menthol, USP

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 201-939-0

Ethyl alcohol (ethanol)

California Proposition 65 developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 200-578-6

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b) Present

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Australia (AICS):
EU EINECS List

Present
200-289-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.

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

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End of Safety Data Sheet