SAFETY DATA SHEET

Sertraline Hydrochloride Tablets, USP

1. IDENTIFICATION

Manufacturer: **Emergency Phone:**

Ascent Pharmaceuticals Inc 1-855-221-1622
400 S. Technology Drive
Central Islip, NY 11722
USA

Common Name: Sertraline Hydrochloride Tablets, USP

Chemical Family: Naphthalenamine derivative.

Synonym(s): No data available.

Chemical Name: 1-Naphthalenamine, 4-(3, 4-dichlorophenyl)-1, 2, 3, 4-tetrahydro-N-methyl-, hydrochloride, (1S-cis)-

Trade Name(s): Sertraline Hydrochloride Tablets, USP 25 mg, 50 mg & 100 mg.

Therapeutic Category: Antidepressant, Anti obsessional, Antipanic agent

Molecular formula: $C_{17}H_{17}Cl_2N.HCl$ **Molecular Weight:** 342.69

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement:
Each Sertraline Hydrochloride Tablet intended for oral administration contains Sertraline Hydrochloride, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

WARNING:

Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Sertraline hydrochloride or any other

antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Sertraline hydrochloride tablets are not approved for the treatment of major depressive disorder in pediatric patients.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: Selective serotonin reuptake inhibitors (SSRIs), Mental depression, Bipolar disorder, Seizure disorders, Liver impairment, Kidney impairment, Recent or concurrent use of monoamine oxidase (MAO) inhibitors**.**

Carcinogenicity: Sertraline Hydrochloride - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	**CAS #**	**Concentration %**		
		25 mg	**50 mg**	**100 mg**
Sertraline Hydrochloride, USP	79559-97-0	≈ 43 %	≈ 43 %	≈ 43 %
Excipients	NA	≈ 57 %	≈ 57 %	≈ 57 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.
* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
The mechanism of action of sertraline is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). Studies at clinically relevant doses in man have demonstrated that sertraline blocks the uptake of serotonin into human platelets. In vitro studies in animals also suggest that sertraline is a potent and selective inhibitor of neuronal serotonin reuptake and has only very weak effects on norepinephrine and dopamine neuronal reuptake. In vitro studies have shown that sertraline has no significant affinity for adrenergic (alpha1, alpha2, beta), cholinergic, GABA, dopaminergic, histaminergic, serotonergic (5HT1A, 5HT1B, 5HT2), or benzodiazepine receptors; antagonism of such receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular effects for other psychotropic drugs.

Overdose Treatment:
Treatment should consist of those general measures employed in the management of overdosage with any antidepressant.Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients.
Activated charcoal should be administered. Due to large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for sertraline are known.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

25 mg Tablets	Green colored film coated, modified capsule shaped tablets, one side debossed with "T" bisect "25" and other side plain.
50 mg Tablets	Blue colored film coated, modified capsule shaped tablets, one side debossed with "T" bisect "50" and other side plain.
100 mg Tablets	Light yellow film coated, modified capsule shaped tablets, one side debossed with "T" bisect "100" and other side plain.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11.TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Sertraline Hydrochloride, USP), and not to the mixture(s) or final formulations.

Inhalation: No data available.

Ingestion: Harmful if swallowed.

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.
Carcinogenesis:
Lifetime carcinogenicity studies were carried out in CD-1 mice and Long-Evans rats at doses up to 40 mg/kg/day. These doses correspond to 1 times (mice) and 2 times (rats) the maximum recommended human dose (MRHD) on a mg/m2 basis. There was a dose-related increase of liver adenomas in male mice receiving sertraline at 10-40 mg/kg (0.25-1.0 times the MRHD on a mg/m2basis). No increase was seen in female mice or in rats of either sex receiving the same treatments, nor was there an increase in hepatocellular carcinomas. Liver adenomas have a variable rate of spontaneous occurrence in the CD-1 mouse and are of unknown significance to humans. There was an increase in follicular adenomas of the thyroid in female rats receiving sertraline at 40 mg/kg (2 times the MRHD on a mg/m2 basis); this was not accompanied by thyroid hyperplasia. While there was an increase in uterine adenocarcinomas in rats receiving sertraline at 10-40 mg/kg (0.5-2.0 times the MRHD on a mg/m2 basis) compared to placebo controls, this effect was not clearly drug related.

Mutagenesis:
Sertraline had no genotoxic effects, with or without metabolic activation, based on the following assays: bacterial mutation assay; mouse lymphoma mutation assay; and tests for cytogenetic aberrations in vivo in mouse bone marrow and in vitro in human lymphocytes.

Impairment of Fertility:
A decrease in fertility was seen in one of two rat studies at a dose of 80 mg/kg (4 times the maximum recommended human dose on a mg/m2 basis).

Other information:
Medically adverse effects reported with Sertraline Hydrochloride Tablets include: Ejaculation Failure, Mouth Dry, Sweating Increased, Somnolence, Dizziness, Headache, Paresthesia, Tremor, Rash, Anorexia, Constipation, Diarrhea/Loose Stools, Dyspepsia, Nausea, Vomiting, Fatigue, Agitation, Anxiety, Insomnia, Libido Decreased, Nervousness, Vision Abnormal.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Sertraline Hydrochloride, USP), and not to the mixture(s) or final formulations.
Ecotoxicity Effects:

Acute toxicity to Fish: No data available.

Acute toxicity to Aquatic Invertebrates: No data available.

Toxicity to Aquatic Plants: No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceuticals, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:
New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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