


# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078948566

N/A

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|  | <b>AUROBINDO PHARMA LIMITED, UNIT – VIII</b> |                       | <b>Page<br/>1 of 4</b> |
|   | <b>MATERIAL SAFETY DATA SHEET</b>            |                       |                        |
| <b>Product</b>  | <b>Sertraline Hydrochloride</b>              | <b>Version No.</b>    | <b>00</b>              |
| <b>MSDS No.</b>   | <b>MSDS/FP/SH</b>                            | <b>Effective Date</b> | <b>05/08/2005</b>      |

### 1 Identification of the substance/preparation and of the company/undertaking

**Product name** : SERTRALINE HYDROCHLORIDE  
**Chemical formula** : C<sub>17</sub>H<sub>17</sub>Cl<sub>2</sub>N.HCl  
**Synonym** : SERTRALINE HYDROCHLORIDE  
**Manufacturer / Supplier** : M/s. AUROBINDO PHARMA LIMITED,  
PLOT NO. : 2, MAITHRIVIHAR COMPLEX,  
AMEERPET, HYDERABAD – 500 038.

### 2 Composition / information on ingredients

**Substance/Preparation** : Substance  
**Chemical name** : Cis-(1S,4S)-N-Methyl-4-(3,4dichlorophenyl)-1,2,3,4-tetrahydro-1-naphthalen amine hydrochloride  
**CAS No.** : [ 79559-97-0 ]

### 3 Hazards identification


**Physical/chemical hazards** : Not applicable.  
**Human health hazards** : WARNING!

If Inhale may cause irritate Avoid inhalation remove fresh air, If eye content may cause mydriasis flush with copious quantities of water, If skin contact May cause irritation. Flush with water. CNS toxicity and an increased heart rate were reported in a neonate whose mother had received 20 mg of Sertraline Hydrochloride daily through out most of her pregnancy. The neonates' symptoms resolved 96 hours after delivery.

### 4 First-aid measures

#### Effects and symptoms

**Inhalation** : May cause irritation. Avoid inhalation remove to fresh air.  
**Ingestion** : Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.  
**Skin Contact** : Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.  
**Aggravating condition** : None for occupational exposure.

|   |  |                       |                        |
|---|--|-----------------------|------------------------|
|  | <b>AUROBINDO PHARMA LIMITED, UNIT – VIII</b> |                       | <b>Page<br/>2 of 4</b> |
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## 5 Fire-fighting measures

**Flammability of the Product** : May be combustible at high temperature.

### Extinguishing Media

**Suitable** : SMALL FIRE: Use DRY chemical powder.  
LARGE FIRE: Use water spray with fog or foam. Do not use water jet.

**Hazardous thermal (de)composition products** : These products are carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>...).

**Special fire-fighting procedures** : Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## 6 Accidental release measures

**Personal precautions** : Wear protective clothing and equipment consistent with the degree of hazard.

**Small Spill and Leak** : Use appropriate tools to put the spilled solid in a convenient waste disposal container.

**Large Spill and Leak** : Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Prevent entry into sewers, basements or confined areas; dike if needed.

## 7 Handling and storage


**Handling** : Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Avoid contact with skin. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label.

**Storage** : Stored in a well closed container at controlled room temperature (between 15°C to 30°C).

## 8 Exposure controls/personal protection

**Engineering measures** : Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Hygiene measures** : Wash hands, forearms, and face thoroughly after handling compounds and before eating, smoking, using lavatory, and at the end of day.

|   |  |                       |                        |
|---|--|-----------------------|------------------------|
|  | <b>AUROBINDO PHARMA LIMITED, UNIT – VIII</b> |                       | <b>Page<br/>3 of 4</b> |
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**Personal protective equipment**

**Respiratory system** : Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.

**Skin and body** : Lab coat.

**Hands** : Gloves.

**Eyes** : Safety glasses.

**Protective Clothing (Pictograms)** :



**9 Physical and chemical properties**

**Appearance and Odour** : A white, crystalline powder.

**Molecular Weight** : 342.7

**Solubility** : Sparingly soluble in ethanol, slightly soluble in water and in isopropyl alcohol

**Flash point** : Not available.


**Explosive properties** : Risks of explosion of the product in presence of mechanical impact : Not available.  
Risks of explosion of the product in presence of static discharge : Not available.

**10 Stability and reactivity**

**Stability** : The product is stable.

**Conditions to avoid** : Sensitive to light.

**Hazardous Decomposition Products** : When heated to decomposition material emits toxic fumes of NO<sub>2</sub> and SO<sub>2</sub> emits toxic fumes under fire conditions.

|   |  |                       |                        |
|---|--|-----------------------|------------------------|
|  | <b>AUROBINDO PHARMA LIMITED, UNIT – VIII</b> |                       | <b>Page<br/>4 of 4</b> |
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## 11 Toxicological information

**Threshold Limit Value** : None established.

**Adverse Effects** : The most common adverse effects with Sertraline Hydrochloride are Nausea, Diarrhoea, Dyspepsia, Drymouth Insomnia, Somnolence, Sweating, Tremor and Delayed Ejaculation. Increased serum trans aminase has occurred. Hyponatraemia, mainly in elderly patients, has been reported rarely.

**Over dose effect** : N/F

**Acute** : Very low incidence of sedation / somnolence.

**Chronic** : Generally well tolerated.

**Inhalation** : Avoid inhalation. Remove to fresh air.

**Ingestion** : May cause irritation. Flush out mouth with water.

**Skin** : May cause irritation. Flush with copious quantities of water.

## 12 Ecological information

**Ecotoxicity** : Not available.

**Toxicity of the Products of Biodegradation** : The products of degradation are less toxic than the product itself.

## 13 Disposal considerations

**Methods of disposal;  
Waste of residues;  
Contaminated packaging** : Waste must be disposed of in accordance with federal, state and local environmental control regulations.

### Notice to Reader

*To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*