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 <b>CADILA</b> <b>PHARMACEUTICALS</b> <small>LIMITED</small> Chemical SBU, Ankleshwar	<b>Safety Data Sheet</b> According to Regulation(EC) No. 453/2010		
	Product Name : FLUOXETINE HYDROCHLORIDE		
	SDS No. : SDS/F1-001	Effective date : 29.01.21	
	Version No. : 03	Review date : 28.01.24	
Department: Environment, Health and Safety		Page No. : 1 of 12	

# 01. CHEMICAL IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER.

## 1.1. Product Identifier

**Trade Name** : Fluoxetine Hydrochloride

**Proper shipping name** : Not a dangerous goods

**Other means of identification** : (±)- N-Methyl-r-[4- (trifluoromethyl)- phenoxy] benzene propanamine; Benzenepropanamine, N- Dimethyl- gamma.- [4-(trifluoromethyl) phenoxy]-, Hydrochloride (9CI).

**Pre-registration number** : No data available

## 1.2. Relevant identification uses of the substances or mixture and uses advised against

### 1.2.1. Relevant identified uses:

Antidepressant, Antiobessional, Antibulimic

### 1.2.2. Uses advised against

Antidepressant, Antiobessional, Antibulimic

## 1.3. Details of the supplier of the safety data sheet:

**Supplier** : Cadila Pharmaceuticals limited

**Address** : Cadila Pharmaceuticals limited, 294, G.I.D.C Estate, Ankleshwar-393 002, Gujarat, India. Phone: +91-2646-251519/252626, Fax: +91-2646-250051.


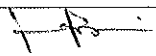
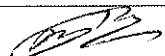
**Telephone** : 91-2646-251519/252626


**Fax** : +91-2646-250051

**Email** : -----

## 1.4. Emergency telephone number

91-2646-251519/252626

	Prepared by	Checked by	Approved by
Name	Hemang Hajariwala	Hasmukh Vamja	Mukesh Patel
Sign			
Date	29.01.21	29.01.21	29.01.21

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## 02. HAZARDS IDENTIFICATION

### 2.1. Classification of substance or mixture:

Harmful if swallowed. Inhaled or absorbed through skin, material may be irritating to mucous membranes and upper respiratory tract GHS CLASSIFICATION: category-1

### 2.2. Label elements

#### Hazard Classification:

None

#### Risk Codes

#### Risk Phrase(S)

R-22: Harmful if swallowed.

R-41: Risk of Serious damage to eyes

#### Safety codes

#### Safety Phrase(s)

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S39 : Wear eye / face protection




S61 : Avoid release to the environment. Refer to special instructions / Safety data sheets

#### Hazard – Statement


H302 : Harmful if swallowed.

H318 : Causes serious eye damage.

#### EUH- Statement

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EUH210 : Safety Data sheet available on request

### Precautionary Statement

P273 : Avoid release to environment

P280 : Wear protective gloves /Eye protection/face protection

P305 + P351 + P338: If in eye : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

### Other Hazard

:-----

### 2.3. Other hazards

No data available

## 03. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances:

**Name** : Fluoxetine Hydrochloride

**Formula Weight** : 345.79

**Molecular Formula** :  $C_{17}H_{18}F_3NO.HCl$

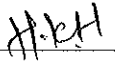
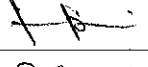

**C.A.S. No** : 56296-78-7

**Synonyms** : +/- N-Methyl-r-[4- (trifluoromethyl)-phenoxy] benzene propanamine, Benzenepropanamine, N- methyl- gamma.-[4- (trifluoromethyl) phenoxy]-, Hydrochloride (9CI).


**EC # No.** : 260-101-2

**N.D.C. No** : 65691-0028-1

**Classification** : H302, H318, Xi, N ,R22.R41

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**Concentration** : Not Less Than 98%

### 3.2. Mixtures

Not applicable

## 04. FIRST-AID MEASURES

### 4.1. Description of first aid measures

The most frequent adverse effect are nausea, diarrhea, anorexia and weight loss, excessive sweating, dyspepsia, rash and/or urticarial, pruritus, increased appetite, and adverse gastrointestinal effects.

#### In case of inhalation:-

Inhalation may cause irritation to the upper respiratory tract. Symptoms may include coughing, shortness of breath and chest pain. Other symptoms may parallel those from ingestion.

#### In case of contact with skin:

Immediately wash skin with soap. May cause irritation, redness and pain.

#### In case of contact with eyes:

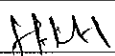

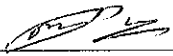
Immediately flush eyes with copious amounts of water. May cause irritation, redness and pain.


#### In case of ingestion:

Harmful if swallowed. Effects of overdose of Fluoxetine Hydrochloride include agitation, restlessness, drowsiness, excitement, fast heartbeat, tremor, diarrhea, nausea or vomiting and seizures. As a psychoactive drug, Fluoxetine causes various neurologic and psychological effects at therapeutic doses.

#### Chronic Exposure:

May cause allergic skin reactions. Super therapeutic doses, in the range of 90 to 120 mg/day, can produce anorexia and weight loss. There is some potential for misuse of Fluoxetine by patients with mood disorders.

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**Aggravation of Pre-existing Conditions:**

Hypersensitive persons or persons with pre-existing liver, kidney, or blood disorders, or cardiac disease may be more susceptible to the effects of this substance.

**4.2. Most important symptoms and effects, both acute and delayed:**

No data available

**4.3. Indication of any immediate medical attention and special treatment needed.**

No data available

**05. FIRE FIGHTING MEASURES**

**Fire:** As with most organic solids, fire is possible at elevated temperature or by contact with an ignition source.

**Explosion-** Fine dust dispersed in air in sufficient concentration, and in the presence of an ignition source is a potential dust explosion hazard.

**5.1. Extinguishing Media: Suitable extinguishing media**

Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

**5.2. Special personal protective equipment and firefighting procedures:**

Unusual fire and explosion hazards: Emits toxic fumes under fire conditions.

Main combustion gas: Not data available.

**5.3. Advice for firefighters:**

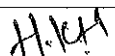
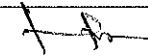
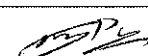
Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

**06. ACCIDENTAL RELEASE MEASURES**


**6.1. Personal precautions, protective equipment and emergency procedures:**

**6.1.1. For non-emergency personal**

Wear suitable protective equipment.

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#### 6.1.2. For emergency responders

Remove all source of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Wear self-contained breathing apparatus, rubber gloves & heavy rubber gloves.

#### 6.2. Environmental precautions

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Turn leaking containers up to prevent further Evacuate area.

#### 6.3. Method and material for containment and cleaning up.

Sweep-up / absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

#### 6.4. Reference to other sections

Personal protective equipment advice is contained in section 8 of SDS.

### 07. HANDLING AND STORAGE

**7.1: Precaution for safe handling:** Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide ventilation at place at where dust is formed. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

**7.2 Condition for storage, including any in compatibilities:** Store in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage.

**7.3. Specific end use(s):** Apart from the uses mentioned in section 1.2.no other specific uses are stipulated.

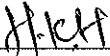
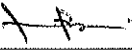
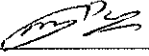
### 08. EXPOSURE CONTROL/PERSONAL PROTECTION


#### 8.1. Control parameters:

Substance: Fluoxetine HCL

CAS No.: 56296-78-7

#### Air born Exposure Limits

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None established.

## 8.2 Exposure controls:

### Ventilation System

A System of Local and general exhaust is recommended to keep employee exposure as low as possible. Local exhaust ventilation is generally preferred because it can control the emission of the contaminants as its sources, preventing dispersion of it in to the general work area.

### Respiratory Protection:

For condition of use for exposure to the dust is apparent, a half-face dust / mist respirator may be worn. For emergencies or instance when the exposure level are not known, use full face positive pressure, air supplied respirator.

**Warning:** Air purifying respirators do not protect workers in Oxygen deficient atmosphere.

### Eye protection:

Use chemical safety goggles and / or a full-face shield when splashing is possible. Maintain eye wash fountain and quick facilities in work area.


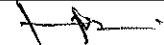

### Skin Protection:


Wear impervious protection clothing, including boots, gloves, lab coats, apron or coveralls as Appropriate, to prevent skin contact.

Use goggles, lab coat, mask, Hand gloves appropriately.

(Pictograms)




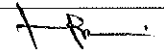
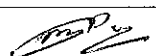
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## 09. PHYSICAL AND CHEMICAL PROPERTIES


### 9.1. Information on basic physical and chemical properties:

<b>Appearance</b>	: White to off crystalline powder
<b>Odor</b>	: No data available
<b>Odor Threshold</b>	: No data available
<b>PH.</b>	: Between 4.5 and 6.5
<b>Melting point / Freezing point</b>	: 158°C to 159°C
<b>Boiling point / range</b>	: No data available
<b>Flash point</b>	: No data available
<b>Evaporation rate</b>	: No data available
<b>Flammability (Solid, gas).</b>	: No data available
<b>LEL / UEL</b>	: No data available
<b>Vapor pressure</b>	: No data available
<b>Vapor density</b>	: No data available
<b>Relative density</b>	: No data available
<b>Solubility</b>	: Sparingly Soluble in water and in dichloromethane, freely soluble in alcohol and in methanol, practically insoluble in ether.
<b>Partition coefficient: (n-octane/water)</b>	: No data available
<b>Auto Ignition Temperature</b>	: No data available
<b>Decomposition</b>	: No data available

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**Temperature****Oxidizing property** : No data available**Explosive property** : No data available**Viscosity** : No data available**Bulk density** : No data available**Upper / lower flammability** : No data available**Odor threshold** : No data available**9.2. Other Information**

No data available.

**10. STABILITY AND REACTIVITY****10.1. Reactivity:**

See Section 7.2

**10.2. Chemical Stability**

Stable at normal temperature and pressure

**10.3. Possibility of Hazardous reactions**

Un Known

**10.4. Conditions to be avoided:**

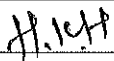
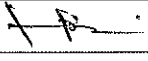
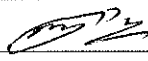
Un Known


**10.5. Substances to be avoided:**

May react with Strong oxidizing agents (e.g. peroxides, permanganates, nitric acid etc.)

**10.6. Hazardous decomposition products:**

May emit carbon monoxide, carbon dioxide, hydrogen chloride, hydrogen fluoride when heated to decomposition

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## 11. TOXICOLOGICAL INFORMATION

### Oral Toxicity

LD50 Orally (Rat) : 452 Mg/kg

Acute Toxicity : LD50 Orally in mice 248mg/kg

## 12. ECOLOGICAL INFORMATION

### 12.1. Eco toxicity

(Aquatic and terrestrial, where available) : No data available

12.2. Persistence and degradability : No data available

12.3. Bio accumulative concentration. : No data available

12.4. Mobility in soil : No data available

12.5. Results of PBT and vPvB assessment : No data available

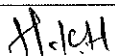
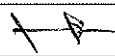
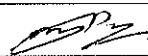
12.6. Other adverse effect. : Toxic to Aquatic Life

## 13. DISPOSAL CONSIDERATIONS


### 13.1. Waste treatment methods

**Product Disposal:** Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation.

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**Contaminated packaging:** Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

#### 14. TRANSPORT INFORMATION

Transport	Road (ADR/RID)	Sea (IMDG)	Air (IATA)	Inland water ways (ANDR)
UN Number	---	---	---	:---
UN proper shipping name	Not dangerous goods	Not dangerous goods	Not dangerous goods	:---
Transport hazard class(as)	---	---	---	:---
Packing group if available	---	---	---	:---
Marine pollutant (Yes/No) / Environment hazard	No	No	No	:---
Special precautions	:---	:---	:---	:---

#### 15. REGULATORY INFORMATION

**15.1: Safety, health and environmental regulations specific for the substance or mixture**

##### 15.1.1. EU regulation

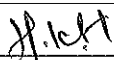
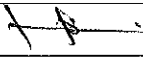
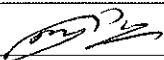
No Data available

##### 15.1.2. International / National regulations.


No data available

##### 15.2: Chemical safety assessment

No chemical safety assessment has been carried out for this substance by the supplier.

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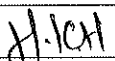
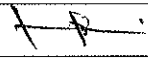
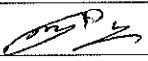
## 16. OTHER INFORMATION

### 16.1. Indication of changes

No data available

### 16.2. Key literature references and sources for data:

The information published in this Safety Data Sheet has been compiled data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions. We reserve the right to revise Safety Data Sheet periodically as new information becomes available. Revision:-03 prepared on dated 29.01.2021 Time: - 12.00 Hrs.

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