

## SAFETY DATA SHEET (SDS)

### Fluoxetine Capsules USP, 10 mg, 20 mg and 40 mg

Revision Date: 12-October-2023

Version 2.0

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

**Product Name:** Fluoxetine Capsules USP, 10 mg, 20 mg and 40 mg

**Product Information:** Fluoxetine Capsules, USP

**Company Name:** Cadila Pharmaceuticals Limited

**Address:** 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

**Phone No.:** 02714/221481

**Fax No.:** 02714/220315

#### 2. HAZARD(S) IDENTIFICATION:

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, inhalation	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
Signal word	Danger	
Hazard statement	H315: Causes skin irritation.	
	H318: Causes serious eye damage.	
	H332: Harmful if inhaled.	
	H336: May cause drowsiness or dizziness	
	H373: May cause damage to organs (Liver) through prolonged or repeated exposure.	

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#### Precautionary statement

Prevention	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	P304 + P340: IF INHALED Remove person to fresh air and keep comfortable for breathing. P305 + P351 +P338: IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor.
Storage	None available.
Disposal	None available.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Name:** (±)-*N*-Methyl-3-phenyl-3-[( $\alpha,\alpha,\alpha$ -trifluoro-*p*-tolyl)oxy] propylamine, hydrochloride

**Product Code:** Not applicable

**Hazardous Ingredients / Components:** Not Applicable

**CAS No.:** 59333-67-4

#### Other Components:

Inactive Ingredients	Exposure Limit	CAS No.
Pregelatinized Starch	Not Found	9005-25-8
Gelatin	Not Found	9000-70-8
Sodium Lauryl Sulphate	Not Found	151-21-3
Titanium Dioxide	Not Found	13463-67-7
Iron Oxide Yellow	Not Found	1309-33-7
FD& C Blue1	Not Found	3844-45-9
FD& C Yellow 6	Not Found	2783-94-0
Shellac	Not Found	9000-59-3
Black Iron Oxide	Not Found	1317-61-9
Propylene Glycol	Not Found	57-55-6
Potassium Hydroxide	Not Found	1310-58-3
Dehydrated Alcohol	Not Found	64-17-5
Isopropyl Alcohol	Not Found	67-63-0
Butyl Alcohol	Not Found	71-36-3
Strong Ammonia Solution	Not Found	1336-21-6

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#### 4. FIRST – AID MEASURES

<b>Inhalation</b>	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
<b>Skin Contact</b>	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye Contact</b>	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately.
<b>Ingestion:</b>	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
<b>Most important symptoms/effects, acute and delayed:</b>	Causes eye burns. May cause drowsiness or dizziness. Increased heart rate. Seizures. May cause damage to the liver.
<b>Indication of immediate medical attention and special treatment needed:</b>	Fluoxetine Hydrochloride - Cardiac and vital signs monitoring is recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In limited human overdose experience, seizures have been reported. Appropriate seizure precautions are advised for any patient regularly taking fluoxetine who has been exposed to an acute overdose. Based on experience in animals, which may not be relevant to humans, fluoxetine-induced seizures that fail to remit spontaneously may respond to diazepam.
<b>General information:</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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#### 5. FIRE FIGHTING MEASURES

**Suitable extinguishing media** Water. Carbon dioxide (co2). Dry chemical.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** Hazardous decomposition products formed under fire conditions.

**Special protective equipment and precautions for firefighters** Wear self-contained breathing apparatus and protective clothing.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures** Wear suitable protective clothing, gloves and eye/face protection. Do not breathe dust. See Section 8 of the SDS for Personal Protective Equipment.

**Methods and materials for containment and cleaning up** The following are recommended for manufacturing or other situations where exposure to contents may occur. Do not sweep. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

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#### 7. HANDLING AND STORAGE

**Precautions to Be Taken in Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

**Precautions to Be Taken in Storing:** Keep container tightly closed. Keep cool. Store in a dry place. Protect from sunlight.

**Storage:** Store at 20° to 25°C (68° to 77°F); excursion permitted to 15° to 30°C (59° to 86° F). [See USP Controlled Room Temperature]

#### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

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

**Personal protection equipment:**

- **Eye Protection:** Safety glasses
- **Protective Gloves:** Compatible chemical-resistant gloves
- **Other Protective Clothing:** Lab coat

**Respiratory Equipment (Specify Type):** NIOSH approved respirator, as conditions warrant.

- **Work/ Hygienic:** Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.

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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:**

**Fluoxetine capsules USP, 10 mg**

White to off white powder filled in size “4” hard gelatin capsules with green opaque cap and green opaque body imprinted “C28”.

**Fluoxetine capsules USP, 20 mg**

White to off white powder filled in size “2” hard gelatin capsules with green opaque cap and yellow opaque body imprinted “C29”.

**Fluoxetine capsules USP, 40 mg**

White to off white powder filled in size “0” hard gelatin capsules with green opaque cap and orange opaque body imprinted “C30”.

<b>Odour</b>	Not Applicable
<b>pH</b>	Not Applicable
<b>Melting Point</b>	Not Applicable
<b>Boiling Point</b>	Not Applicable
<b>Flash Point</b>	Not Applicable
<b>Evaporation Rate</b>	Not Applicable
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Explosive Limits</b>	Not Applicable
<b>Vapor Density (vs. Air = 1)</b>	Not Applicable
<b>Pressure (vs. Air or mm Hg)</b>	Not Applicable
<b>Specific Gravity (Water = 1)</b>	Not Applicable
<b>Solubility in Water</b>	Sparingly Soluble
<b>Solubility Notes</b>	Not Applicable
<b>Octanol/Water Partition Coefficient</b>	Not Applicable
<b>Autoignition Point</b>	Not Applicable
<b>Decomposition Temperature</b>	Not Applicable
<b>Viscosity</b>	Not Applicable
<b>Other Information:</b>	Sparingly soluble in water and in dichloromethane, freely soluble in alcohol and in methanol; practically insoluble in ether.
<b>Molecular formula:</b>	C <sub>17</sub> H <sub>18</sub> F <sub>3</sub> NO · HCl
<b>Molecular weight:</b>	345.79 g/mol

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#### 10. STABILITY AND REACTIVITY

**Reactivity:** Not Applicable

**Stability Note(s):** Stable if stored in accordance with information listed on the product insert.

**Incompatibility – Materials:** strong oxidizing agents

**Hazardous Decomposition Product(s):** carbon dioxide, carbon monoxide, hydrogen chloride gas, hydrogen fluoride and nitrogen oxides

#### 11. TOXICOLOGY INFORMATION

**Toxicological Effects:** The toxicological effects of this product have not been thoroughly studied. Fluoxetine (hydrochloride) - Toxicity Data: Oral TDLO (human): 7770 ug/kg; Oral TDLO (woman): 5600 µg/kg/2W (intermittent); Oral LD50 (rat): 452 mg/kg; Oral LD50 (mouse): 248 mg/kg; Intraperitoneal LD50 (mouse): 100 mg/kg; Subcutaneous TDLO (mouse): 1 mg/kg; Intraperitoneal TDLO (rat): 10 mg/kg; Subcutaneous TDLO (rat): 5 mg/kg.

**Chronic Toxicological:** Fluoxetine (hydrochloride) - Investigated as a drug, mutagen, and reproductive effector. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Fluoxetine (hydrochloride) RTECS Number: UI4050000.

#### 12. ECOLOGICAL INFORMATION

**Toxicity:** Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

**Persistence and Degradability:** Not Applicable

**Mobility in Soil:** Not Applicable

**Bioaccumulative Potential:** Not Applicable

**Results of PBT and vPvB assessment:** Not Applicable

**Other adverse effects:** Not Applicable

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#### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state, and federal regulations.

#### 14. TRANSPORT INFORMATION

<b>U.S. Department of Transportation</b>	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101
<b>Transport Canada Transportation of Dangerous Goods Regulations</b>	This material does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada
<b>International Air Transport Association (IATA):</b>	This product does not meet the criteria as Dangerous Goods, per rules of IATA
<b>International Maritime Organization Designation (IMO)</b>	This product is NOT classified as Dangerous Goods by the International Maritime Organization.
<b>European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)</b>	Does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
<b>Transport in Bulk according to the IBC CODE</b>	Not applicable.
<b>Environmental hazards</b>	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is not specifically listed in Annex III under MARPOL 73/78



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#### 15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is 206993.

#### 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this MSDS.