



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Fluoxetine Hydrochloride	
Other means of identification		
Catalog number	1279804	
CAS number	56296-78-7	
Chemical name	(±)-N-methyl-3-phenyl-3-[(alpha,alpha,alpha-trifluoro-p-tolyl)oxy]propylamine hydrochloride	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Acute toxicity, inhalation	Category 2
	Serious eye damage/eye irritation	Category 1
	Reproductive toxicity	Category 2
<b>Environmental hazards</b>	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. Causes serious eye damage. Fatal if inhaled. Suspected of damaging fertility or the unborn child.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.

<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: Get medical advice/attention. Immediately call a poison center/doctor.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Fluoxetine Hydrochloride		56296-78-7	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Call a physician or poison control center immediately.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse cautiously with water for several minutes. Call a physician or poison control center immediately. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Do not induce vomiting. Perform gastric lavage. Administer activated charcoal with sorbitol to decrease absorption. Monitor cardiac function. Maintain respiratory function. Maintain body temperature. For seizures, administer diazepam intravenously.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

Industrial Use Material	Type	Value	Form
Fluoxetine Hydrochloride (CAS 56296-78-7)	STEL	50 micrograms/m3	8 hours
		30 micrograms/m3	12 hours

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Powder.

#### Color

White.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

316.4 - 325.4 °F (158 - 163 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** 0.000003 kPa at 25 °C

**Vapor density** Not available.

**Relative density** Not available.

**Solubility(ies)**

**Solubility (water)** Sparingly soluble.

**Solubility (other)** Ether: Practically insoluble.  
Dichloromethane: Sparingly soluble.  
Alcohol: Freely soluble.  
Methanol: Freely soluble.

**Partition coefficient (n-octanol/water)** 1.8 at pH 7

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other information**

**Chemical family** Cyclic propylamine derivative.

**Molecular formula** C17H18F3NO.HCl

**Molecular weight** 345.79

345.79 g/mol

**pH in aqueous solution** 4.5 - 6.5 Solution: 1%

**10. Stability and reactivity**

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

**Incompatible materials** Oxidizing agents. Strong bases.

**Hazardous decomposition products** NOx. Cl-. F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

**11. Toxicological information****Information on likely routes of exposure**

**Inhalation** Fatal if inhaled.

**Skin contact** Knowledge about health hazard is incomplete.

**Eye contact** Causes serious eye damage.

**Ingestion** Harmful if swallowed.

**Symptoms related to the physical, chemical, and toxicological characteristics** Selective serotonin reuptake inhibitors (SSRIs): Agitation. Nervousness. Confusion. Headache. Tiredness. Dizziness. Insomnia. Blurred vision. Tremor. Weakness. Motor restlessness. Body aches or pain. Dilated pupils. Fever. Sweating. Increased urination. Dry mouth. Gastrointestinal disturbances. Decreased or increased appetite. Skin rash. Decreased sexual ability or desire. Absence of menstrual period. Discharge of milk-like substance from the breast. Fast heart rate.

**Information on toxicological effects**

**Acute toxicity** Fatal if inhaled. Harmful if swallowed.

Product	Species	Test Results
Fluoxetine Hydrochloride (CAS 56296-78-7)		
<b>Oral</b>		
LD50	Rat	452 mg/kg
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 500 mg/kg
<b>Inhalation</b>		
LC50	Rat	0.2 mg/l
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.	
<b>Local effects</b>		
Eye irritation		
Result: Corrosive.		
Species: Rabbit		
Organ: Eye.		
Skin irritation		
Result: Negative.		
Species: Rabbit		
Organ: Skin.		
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Mutagenicity</b>		
Mutagenicity, Bacterial mutation assay		
Result: Negative.		
Mutagenicity, DNA repair assay in cultured rat hepatocytes		
Result: Negative.		
Mutagenicity, In vivo sister chromatid exchange assay in Chinese hamster bone marrow cells		
Result: Negative.		
Mutagenicity, Lymphoma assay		
Result: Negative.		
Species: Mouse		
<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.	
Carcinogenicity		
Result: Negative.		
Species: Rat		
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	Suspected of damaging fertility or the unborn child. Therapeutic use of SSRIs late in pregnancy may be associated with a transient syndrome of central nervous system, motor, respiratory, and gastrointestinal effects in the newborn.	
<b>Reproductivity</b>		
12 mg/kg/day Reproductivity		
Result: Impaired pup survival and decreased birth weight.		
Species: Rat		
<b>Specific target organ toxicity - single exposure</b>	Knowledge about health hazard is incomplete.	
<b>Specific target organ toxicity - repeated exposure</b>	Knowledge about health hazard is incomplete.	
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.	

**Further information**

Pharmacologically active material. Occupational exposure may cause physiological effects.

**12. Ecological information****Ecotoxicity**

Very toxic to aquatic life with long lasting effects.

Product	Species		Test Results
Fluoxetine Hydrochloride (CAS 56296-78-7)			
Aquatic			
Acute			
Crustacea	IC50	Daphnia magna	0.94 mg/l, 48 hours
Fish	LC50	Rainbow Trout	1.57 mg/l, 96 hours

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential****Octanol/water partition coefficient log Kow**

1.8, at pH 7

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

**13. Disposal considerations****Disposal instructions**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations**

Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products**

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

UN number	UN2811
UN proper shipping name	Toxic solids, organic, n.o.s. (Fluoxetine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

**IATA**

UN number	UN2811
UN proper shipping name	Toxic, organic, n.o.s. (Fluoxetine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

DOT; IATA



**General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

**15. Regulatory information**

**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

Yes

**Classified hazard categories**

Acute toxicity (any route of exposure)  
Serious eye damage or eye irritation  
Reproductive toxicity

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)  
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	02-27-2006
<b>Revision date</b>	11-27-2018
<b>Version #</b>	06
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