



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Atomoxetine Hydrochloride</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1044469	
<b>CAS number</b>	82248-59-7	
<b>Chemical name</b>	(-)-N-Methyl-3-phenyl-3-(o-tolyloxy)-propylamine hydrochloride	
<b>Recommended use</b>	For analytical laboratory use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	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 3
	Acute toxicity, inhalation	Category 2
	Serious eye damage/eye irritation	Category 1
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Toxic if swallowed. Causes serious eye damage. Fatal if inhaled.
<b>Precautionary statement</b>	
<b>Prevention</b>	Do not breathe dust. Wash thoroughly after handling. Wear eye protection/face protection. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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.

Supplemental information Potent pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Atomoxetine Hydrochloride		82248-59-7	100

### 4. First-aid measures

**Inhalation** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.

**Skin contact** Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact** Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

**Ingestion** Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Most important symptoms/effects, acute and delayed** Serotonin syndrome. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Treatment of SNRI (Serotonin and norepinephrine reuptake inhibitor) overdose may include the following: Gastrointestinal decontamination with activated charcoal is recommended. Maintenance of airway, breathing, circulatory status of the patient, in addition to ECG monitoring is warranted. Clinical assessment for signs that may indicate impending seizure activity or serotonin toxicity is important. Active measures should be taken to control muscular activity, lower temperature, and preserve renal function. Cyproheptadine may reverse serotonin toxicity.

**General information** 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

**Suitable extinguishing media** Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters** Wear suitable protective equipment.

**Fire fighting equipment/instructions** 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.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

### 6. Accidental release measures

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

**Methods and materials for containment and cleaning up** 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. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP materials, 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.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. 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

<b>Industrial Use Material</b>	<b>Type</b>	<b>Value</b>
Atomoxetine Hydrochloride (CAS 82248-59-7)	TWA	38 micrograms/m3

### Biological limit values

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

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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

Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover 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

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	White. Off-white.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	321.8 - 329 °F (161 - 165 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

**Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.

**Solubility(ies)**

<b>Solubility (water)</b>	Soluble.
<b>Solubility (other)</b>	Methanol: Soluble. Ethanol: Soluble. Acetone: Practically insoluble. Toluene: Practically insoluble.

<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

**Other information**

<b>Molecular formula</b>	C17H21NO . HCl
<b>Molecular weight</b>	291.82

**10. Stability and reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong acids. Strong bases.
<b>Hazardous decomposition products</b>	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

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

<b>Inhalation</b>	Fatal if inhaled.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Causes serious eye damage.
<b>Ingestion</b>	Toxic if swallowed. Based on information from therapeutic use, this material may cause: Serotonin syndrome.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	SNRIs (Serotonin and norepinephrine reuptake inhibitors): Mood or mental status changes. Sleep disturbances. Gastrointestinal disturbances. Drowsiness. Dizziness. Fatigue. Headache. Elevated blood pressure. Bleeding.
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**Information on toxicological effects**

<b>Acute toxicity</b>	Fatal if inhaled. Toxic if swallowed.
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<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Atomoxetine Hydrochloride (CAS 82248-59-7)		
<b>Inhalation</b>		
LC50	Rat	330 mg/m3, 4 hours
<b>Oral</b>		
LD50	Rat	196 mg/kg (fasted)

Product	Species	Test Results
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 200 mg/kg
<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>		
Irritancy test		
Result: Irritant.		
Species: Rabbit		
Organ: Eye.		
Severity: Corrosive.		
Irritancy test		
Result: Non-irritant.		
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>		
Chromosomal aberration test in CHO cells		
Result: Negative.		
In vitro mouse lymphoma assay		
Result: Negative.		
In vivo mouse micronucleus test		
Result: Negative.		
Reverse point mutation assay		
Result: Negative.		
Sister chromatid exchange assay		
Result: Negative.		
Unscheduled DNA synthesis test in rat hepatocytes		
Result: Negative.		
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.	
< 458 mg/kg/day Carcinogenicity study		
Result: Not carcinogenic.		
Species: Mouse		
< 47 mg/kg/day Carcinogenicity study		
Result: Not carcinogenic.		
Species: Rat		
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	Not listed.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>	Not listed.	
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>	Not listed.	
<b>Reproductive toxicity</b>	Knowledge about health hazard is incomplete.	
<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.	
<b>Further information</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this substance.

<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

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

#### IATA

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Atomoxetine Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	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.

#### Toxic Substances Control Act (TSCA)

##### 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 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes**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 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. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	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>	06-24-2010
<b>Revision date</b>	03-16-2021
<b>Version #</b>	03

**Disclaimer**

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