



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Duloxetine Hydrochloride USP

30-4999

Section 1: Identification

Product Name Duloxetine Hydrochloride USP

Commercial Name N/A

Product Use Antidepressant

Restrictions On Use N/A

Product Code 30-4999

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute Toxicity oral Category 3 Serious Eye damage/eye irritation Category 1
CFR 1910.1200

Signal Word WARNING

Hazard Statement(s) Toxic if swallowed.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention	Wash thoroughly after handling. Wear eye protection/face protection
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. 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.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Duloxetine Hydrochloride
% By Weight	100
CAS#	136434-34-9
Molecular Weight	333
Chemical Formula	C ₁₈ H ₁₉ NOS.HCl
Synonym(s)	(+)-(S)-N-methyl-gamma-(1-naphthoxy)2-thiophenepropylamine hydrochloride

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Duloxetine Hydrochloride	136434-34-9	100	N/A	N/A

Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist
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 thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. 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.
Symptoms/Effects	
Acute	Serotonin syndrome. Pharmacologically active material. Occupational exposure may cause physiological effects
Delayed	Serotonin syndrome. Pharmacologically active material. Occupational exposure may cause physiological effects
Immediate Medical Attention	Provide general supportive measures and treat symptomatically.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials

Unsuitable Extinguishing Media

Not available

Products of Combustion

No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. 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. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

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.

Section 7: Handling and Storage

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

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA: 40 micrograms/m ³ (8 hours) 300 micrograms/m ³ (30 minute excursion) 25 micrograms/m ³ (12 hours)
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.

Personal Protection

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.

Section 9: Physical and Chemical Properties

Appearance	White. Off-white. powder. solid.		
Odor	Odorless		
Odor Threshold	N/A		
Melting Point	329 - 339.8 °F (165 - 171 °C)	pH	Not available
Freezing Point	N/A	Vapor Pressure	N/A
Boiling Point/Range	N/A	Vapor Density	N/A
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	Not available	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	N/A
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	Slightly soluble in water.		
Other	Chemical family Naphthyl ether amine. Molecular formula C18H19NOS . HCl Molecular weight 333.88		

Section 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.
Hazardous Polymerization	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	NOx. SOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

Section 11: Toxicological Information

RTECS	N/A
Acute Toxicity	Oral LD50 Rat 491 mg/kg (male), 279 mg/kg (female)
Skin Corrosion/Irritation	Not available.
Serious Eye Damage/Irritation	Causes serious eye damage.
Respiratory or Skin Sensitization	Not available
Germ Cell Mutagenicity	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Routes of Entry	Eye. Ingestion.

Symptoms Related to Exposure

SNRIs (Serotonin and norepinephrine reuptake inhibitors): Mood or mental status changes. Sleep disturbances. Gastrointestinal disturbances. Drowsiness. Dizziness. Fatigue. Headache. Elevated blood pressure. Bleeding.

Potential Health Effects

N/A

Target Organ(s)

N/A

Section 12: Ecological Information**Ecotoxicity**

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.

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

Mobility in Soil

Not available

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

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

Disposal of Container

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

Other Considerations

N/A

Section 14: Transport Information**DOT Classification**

DOT UN2811 UN number Toxic solid, organic, n.o.s. (Duloxetine Hydrochloride) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing group III

Section 15: Regulatory Information**Regulations**

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. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Serious eye damage or eye irritation Classified hazard categories 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. Not regulated. Safe Drinking Water Act (SDWA) 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.

Other

N/A



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Section 16: Other Information

Indication of changes No information available. Abbreviation and acronyms No information available. Relevant R-Phrases (Number and full text) R22: Harmful if swallowed. R36/38: Irritating to eyes and skin. Training instructions No information available.