

1. Identification

Product identifier	Paroxetine Hydrochloride	
Other means of identification		
Catalog number	1500218	
CAS number	110429-35-1	
Chemical name	Piperidine, 3-[(1,3-benzodioxol-5-yloxy)methyl]-4-(4-fluorophenyl)-,(3S-trans)-, hydrochloride, hemihydrate with 1-methyl-4-(p-fluorophenyl)-1,2,3,6-tetrahydropyridine	
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

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 1
	Reproductive toxicity	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. Causes serious eye damage. May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Call a poison center/doctor if you feel unwell. 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. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Paroxetine Hydrochloride		110429-35-1	100

4. First-aid measures

Inhalation	Move to fresh air. 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	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Rinse mouth. 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.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment may include the following: Do not induce vomiting. To decrease absorption, perform gastric lavage and administer activated charcoal as a slurry. Monitor cardiac and central nervous system function; establish and monitor airway; monitor vital signs. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For seizures, administer an intravenous benzodiazepine. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For serotonin syndrome, administer cyproheptadine orally. Due to the large volume distribution of paroxetine, forced diuresis, hemodialysis, hemoperfusion, or exchange transfusions are not likely to be of benefit.
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 CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
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. Cool containers exposed to flames with water until well after the fire is out.
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. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.
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Methods and materials for containment and cleaning up

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.

Environmental precautions

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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). 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**

Paroxetine Hydrochloride
(CAS 110429-35-1)

TWA

40 micrograms/m3

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

Handle in accordance with good industrial hygiene and safety practice. 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

Crystalline powder.

Color

White. Off-white.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

248 - 293 °F (120 - 145 °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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly soluble.
Solubility (other)	Methanol: Soluble.
Partition coefficient (n-octanol/water)	1.3 (pH 7)
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Phenylpiperidine derivative.
Dust explosion properties	
Kst	237 bar.m/s
St class	2 Strong explosion.
Minimum ignition energy (MIE) - dust cloud	3 - 4 mJ
Molecular formula	C19H21ClFNO3 . 1/2H2O
Molecular weight	374.84

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	Strong oxidizing agents. Strong bases.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, Cl-, F-.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
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 Harmful if swallowed.

Product	Species	Test Results
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Paroxetine Hydrochloride (CAS 110429-35-1)

Acute

Oral

LD50	Rat	374 mg/kg
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Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes serious eye damage.

Local effects

Eye irritation test, species not specified

Result: Severe.

Skin irritation test: (Draize)

Result: Irritating to abraded skin, but not irritating to intact skin.

Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Based on available data, the classification criteria are not met.

Guinea pig maximization test

Result: Negative.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Dominant lethal test: In vivo in rats

Result: Not genotoxic.

Mutagenicity: In vitro tests for cytogenetic aberrations in human lymphocytes

Result: Not genotoxic.

Mutagenicity: In vivo tests for cytogenetic aberrations in mouse bone marrow

Result: Not genotoxic.

Mutagenicity: Mouse lymphoma mutation assay

Result: Not genotoxic.

Mutagenicity: Reverse mutation assay in *S. typhimurium*

Result: Not genotoxic.

Mutagenicity: Unscheduled DNA synthesis assay

Result: Not genotoxic.

Carcinogenicity Based on available data, the classification criteria are not met.

1 - 20 mg/kg/day Carcinogenicity

Result: Increased incidence of reticulum cell sarcomas and lymphoreticular tumors in males but not in females.

Species: Rat

Test Duration: 2 years

1 - 25 mg/kg/day Carcinogenicity

Result: Dose-related increase in the amount of tumors, but not in the amount of mice with tumors.

Species: Mouse

Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage fertility or the unborn child.

Epidemiological studies have shown an association between therapeutic use of paroxetine in the first trimester and an increased risk of congenital malformations, particularly cardiac defects, in the newborn.

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.

Reproductivity

15 mg/kg/day Reproductivity: Fertility study

Result: Reduced pregnancy rates in females.

Species: Rat

25 - 50 mg/kg/day Reproductivity: Toxicity study

Result: Irreversible lesions in the reproductive tracts of males; impaired spermatogenesis.

Species: Rat

50 mg/kg/day Reproductivity, administered during organogenesis

Result: Not teratogenic.

Species: Rat

6 mg/kg/day Reproductivity, administered during organogenesis

Result: Not teratogenic.

Species: Rabbit

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard 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

Product	Species		Test Results
Paroxetine Hydrochloride (CAS 110429-35-1)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	2.5 mg/l, 48 hours static
Fish	EC50	Bluegill (Lepomis macrochirus)	1.6 mg/l, 96 hours static

Persistence and degradability Not readily biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
1.3, (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 UN3077

UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Paroxetine hydrochloride)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III

IATA

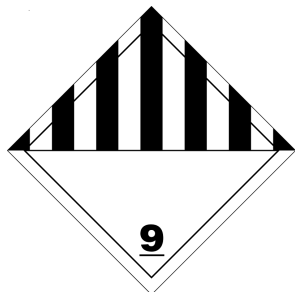
UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Paroxetine hydrochloride)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	

Passenger and cargo aircraft	Allowed with restrictions.
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Cargo aircraft only	Allowed with restrictions.
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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
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DOT; IATA



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

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - Yes
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
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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.

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
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

Issue date 10-20-2010

Revision date 10-18-2018

Version # 04

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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