

1. Identification

| | | |
|--|---|-----------------|
| Product identifier | Paroxetine Related Compound E Mixture | |
| Other means of identification | | |
| Catalog number | 1500262 | |
| Chemical name | Paroxetine hydrochloride spiked 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. | |

3. Composition/information on ingredients

Mixture

| Chemical name | Common name and synonyms | CAS number | % |
|-------------------------------|--------------------------|--------------|---------|
| Paroxetine Hydrochloride | | 78246-49-8 | 99.9995 |
| Paroxetine Related Compound E | | 1012886-75-7 | 0.0005 |

4. First-aid measures

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|---|---|
| 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 | Call a physician or poison control center immediately. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| 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 | Serious eye damage. Reproductive system effects. 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

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| Suitable extinguishing media | Water. Foam. Dry chemical or CO ₂ . 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. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

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| 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. |
| 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
Components****Type****Value**

Paroxetine Hydrochloride
(CAS 78246-49-8)

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**

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

Not available.

**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) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

10. Stability and reactivity

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|------------------------------------|--|
| 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. F-, NOx, Cl-. |

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 | Component: 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. |
|----------------|-----------------------|

| Components | Species | Test Results |
|---|---|--------------|
| Paroxetine Hydrochloride (CAS 78246-49-8) | | |
| <u>Acute</u> | | |
| Oral | | |
| LD50 | Rat | 374 mg/kg |
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | Causes serious eye damage. | |
| Local effects | | |
| Paroxetine Hydrochloride | Eye irritation test, species not specified Result: Severe. | |

Local effects

Paroxetine Hydrochloride

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.

Paroxetine Hydrochloride

Guinea pig maximization test

Result: Negative.

Germ cell mutagenicity

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

Mutagenicity

Paroxetine Hydrochloride

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

Knowledge about carcinogenicity is incomplete.

Paroxetine Hydrochloride

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.

Reproductivity

Paroxetine Hydrochloride

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

| Components | | Species | Test Results |
|---|------|--------------------------------|---------------------------|
| Paroxetine Hydrochloride (CAS 78246-49-8) | | | |
| 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 No data is available on the degradability of this product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Paroxetine Hydrochloride 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

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|--|--|
| 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 Related Compound E Mixture) |
| 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 Related Compound E Mixture) |
| Transport hazard class(es) | |
| Class | 9 |
| Subsidiary risk | - |
| Packing group | III |

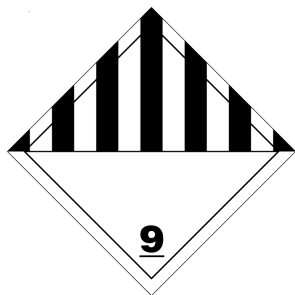
Other information

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 1910.1001-1050)

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

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 |

| Country(s) or region | Inventory name | On inventory (yes/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 | 06-10-2009 |
| Version # | 01 |
| 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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