SAFETY DATA SHEET

1. Identification

Product identifier: Duloxetine Hydrochloride

Other means of identification
- Catalog number: 1229817
- CAS number: 136434-34-9
- Chemical name: (+)-(S)-N-methyl-gamma-(1-naphthyloxy)-2-thiophenepropylamine hydrochloride

Recommended use: Specified quality tests and assay use only.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790 United States
- 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 3
- Serious eye damage/eye irritation: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Signal word: Danger
- Hazard statement: Toxic if swallowed. Causes serious eye damage.
- Precautionary statement
  - 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.

Hazard(s) not otherwise classified (HNOC): None known.

3. Composition/information on ingredients

Substance

Material name: Duloxetine Hydrochloride

1229817 Version #: 04 Revision date: 05-12-2020 Issue date: 07-19-2010
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.

Most important symptoms/effects, acute and delayed
Serotonin syndrome. 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.

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
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
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.

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

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

<table>
<thead>
<tr>
<th>Industrial Use</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duloxetine Hydrochloride (CAS 136434-34-9)</td>
<td>TWA</td>
<td>40 micrograms/m³ (8 hours)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>300 micrograms/m³ (30 minute excursion)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>25 micrograms/m³ (12 hours)</td>
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</tbody>
</table>

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. Off-white.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

329 - 339.8 °F (165 - 171 °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.
Auto-ignition temperature  Not available.
Decomposition temperature  Not available.
Viscosity  Not available.
Other information
  Chemical family  Naphthyl ether amine.
  Molecular formula  C18H19NOS . HCl
  Molecular weight  333.88

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

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  Toxic if swallowed. Based on information from therapeutic use, this material may cause: Serotonin syndrome.
Symptoms related to the physical, chemical and toxicological characteristics
Information on toxicological effects
Acute toxicity  Toxic if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duloxetine Hydrochloride</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>491 mg/kg (male)</td>
</tr>
<tr>
<td></td>
<td>279 mg/kg (female)</td>
</tr>
</tbody>
</table>

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
    Result: Corrosive.
    Species: Rabbit
Skin irritation
    Result: Slight irritation.
    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.
Active/passive anaphylaxis test
Result: Negative.
Species: Guinea pig

Germ cell mutagenicity
Knowledge about mutagenicity is incomplete.

Carcinogenicity
Based on available data, the classification criteria are not met.
- 100 mg/kg/day Carcinogenicity
  Result: Tumor incidence was not increased.
  Species: Mouse
- 140 mg/kg/day Carcinogenicity
  Result: Increased incidence of hepatocellular adenomas and carcinomas.
  Species: Mouse
- 27 mg/kg/day Carcinogenicity
  Result: No increase in incidence of tumors.
  Species: Rat
- 50 mg/kg/day Carcinogenicity
  Result: No effect.
  Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
Knowledge about health hazard is incomplete.
Newborns exposed to SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors) or SSRIs (Selective Serotonin Reuptake Inhibitors) late in the third trimester have developed complications consistent with either a direct toxic effect or a drug discontinuation syndrome.

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
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
No data is available on the degradability of this substance.

Bioaccumulative potential
No data available.

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 solid, organic, n.o.s. (Duloxetine Hydrochloride)
Transport hazard class(es)

Class 6.1
Subsidiary risk -
Packing group III

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Duloxetine Hydrochloride)

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

<table>
<thead>
<tr>
<th>Classified hazard categories</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (any route of exposure)</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage or eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

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.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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 07-19-2010
Revision date 05-12-2020
Version # 04

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