SAFETY DATA SHEET

1. Identification

Product identifier  
Venlafaxine Hydrochloride

Other means of identification
Catalog number  
1711268

Chemical name  
Cyclohexanol, 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]-, hydrochloride

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

Company name  
U. S. Pharmacopeia

Address  
12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

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

OSHA hazard(s)  
Not classified.

Label elements

Signal word  
Warning

Hazard statement  
Harmful if swallowed.

Precautionary statement

Prevention  
Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Response  
Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell.

Storage  
Not available.

Disposal  
Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)  
Not classified.

3. Composition/information on ingredients

Substance  
Venlafaxine Hydrochloride

Hazardous components

Chemical name  
Venlafaxine Hydrochloride

Common name and synonyms  
99300-78-4

%  
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 with water. Get medical attention if irritation develops and persists.

Ingestion  
Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed

Treatment of venlafaxine hydrochloride overdose should be symptomatic and supportive and may include the following:

1. Do not induce vomiting.
2. Administer activated charcoal as a slurry.
3. Consider gastric lavage if it can be performed soon after ingestion. Protect airway and control seizures first.
4. For seizures, administer a benzodiazepine IV. Consider phenobarbital or propofol if seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, need for endotracheal intubation, hypoglycemia, electrolyte disturbances, and hypoxia.
5. Treat QRS widening or ventricular dysrhythmias with sodium bicarbonate, lidocaine, or amiodarone. Atropine may be used for severe bradycardia.
6. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.
7. Dialysis, hemoperfusion, peritoneal dialysis, and repeat-dose charcoal are not likely to be effective. [Poisindex 2009; Poisoning and Drug Overdose 4th edition]

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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

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.

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

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venlafaxine Hydrochloride (CAS 99300-78-4)</td>
<td>TWA</td>
<td>100 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values

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

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White to off-white crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

404.6 - 408.2 °F (207 - 209 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

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

< 0.0000001 kPa at 25 °C

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Freely soluble.

Partition coefficient (n-octanol/water)

0.43

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Bicyclic phenylethylamine derivative.

Molecular formula

C17H27NO2 \cdot HCl

Molecular weight

313.86
10. Stability and reactivity

Reactivity No reactivity hazards known.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid None known.
Incompatible materials Strong oxidizing agents.
Hazardous decomposition products NOx, HCl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Ingestion Harmful if swallowed.
Inhalation Due to lack of data the classification is not possible.
Skin contact Due to lack of data the classification is not possible.
Eye contact Due to lack of data the classification is not possible.

Acute toxicity Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venlafaxine Hydrochloride (CAS 99300-78-4)</td>
<td>Rat</td>
<td>LD50 673 mg/kg, (males)</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>LD50 336 mg/kg, (females)</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Due to lack of data the classification is not possible.
Serious eye damage/eye irritation Due to lack of data the classification is not possible.
Respiratory sensitization Due to lack of data the classification is not possible.
Skin sensitization Due to lack of data the classification is not possible.
Germ cell mutagenicity Due to lack of data the classification is not possible.

Mutagenicity
Ames reverse mutation test in S. typhimurium Result: Negative.
CHO/HGPRT mammalian cell forward gene mutation assay Result: Negative.
In vitro BALB/c-3T3 mouse cell transformation assay Result: Negative.
In vitro sister chromatid exchange in Chinese hamster ovary cells Result: Negative.
In vivo chromosomal aberration assay in rat bone marrow Result: Negative.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
120 mg/kg/day Long-term carcinogenicity study Result: Not tumorigenic.
Species: Mouse
Test Duration: 18 months
120 mg/kg/day Long-term carcinogenicity study Result: Not tumorigenic.
Species: Rat
Test Duration: 24 months
Reproductive toxicity

Based on available data, the classification criteria are not met.
Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.
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.

Reproductivity

45 - 135 mg/kg/day Reproductivity and development study, administered orally during gestation
Result: Increased frequencies of cardiac and skeletal malformations.
Species: Rabbit
7.5 - 70 mg/kg/day Reproductivity and development study, administered by gavage during gestation
Result: No increase in the frequency of congenital anomalies in the offspring.
Species: Rat
Fertility study, administered orally; doses 8 times the maximum human daily dose
Result: No adverse effect.
Species: Rat

Specific target organ toxicity - single exposure
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure
Based on available data, the classification criteria are not met.

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

12. Ecological information

Ecotoxicity

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<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae IC50</td>
<td>Algae</td>
<td>4.8 mg/l, 72 hours</td>
</tr>
<tr>
<td>Crustacea EC50</td>
<td>Daphnia magna</td>
<td>38 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish LC50</td>
<td>Fish</td>
<td>&gt; 100 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
Not inherently biodegradable.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
Do not allow this material to drain into sewers/water supplies. Dispose of waste in accordance with all applicable Federal, State and local laws.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

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
Empty containers should be taken to an approved waste handling site for recycling or disposal. 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. (Venlafaxine Hydrochloride)
Transport hazard class(es): 9
Subsidiary class(es): Not available.
Packing group: III

IATA

UN number: UN3077
UN proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Venlafaxine Hydrochloride)
Transport hazard class(es): 9
Subsidiary class(es): -
15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations

Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
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)

16. Other information, including date of preparation or last revision

Issue date | 10-19-2009
Revision date | 08-09-2013
Version # | 02
Further information | Not available.
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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.