SAFETY DATA SHEET

1. Identification

Product identifier: Hydroxyzine Hydrochloride

Other means of identification

- Catalog number: 1333003
- Chemical name: Ethanol, 2-[2-[4-[4-chlorophenyl]phenethyl]-1-piperazinyl]ethoxy]-, dihydrochloride, (+/-)-
- Synonym(s): Hydroxyzine dihydrochloride

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
- Skin corrosion/irritation: Category 1
- Serious eye damage/eye irritation: Category 1
- Reproductive toxicity: Category 2
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: Harmful if swallowed. Causes severe skin burns and eye damage. May cause drowsiness or dizziness. Suspected of damaging 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. Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. 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/medical professional.

Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC): Not classified.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hydroxyzine Hydrochloride</td>
<td>Hydroxyzine dihydrochloride</td>
<td>2192-20-3</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

**Inhalation**
Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician or poison control center immediately.

**Skin contact**
Rinse skin with water/shower. Call a physician or poison control center immediately.

**Eye contact**
Rinse cautiously with water for several minutes. Call a physician or poison control center immediately.

**Ingestion**
Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed**
Corrosive effects.

**Indication of immediate medical attention and special treatment needed**
Treatment of antihistamine overdose should be symptomatic and supportive and may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry. For delirium, administer phystostigmine. For tachycardia in agitated patients, sedate with benzodiazepines. If severe tachycardia results in hemodynamic compromise or ischemia, administer beta-blocking agents. A short-acting cardioselective agent, such as esmolol, is preferred. Administer intravenous lidocaine. For dysrhythmias, administer sodium bicarbonate. For torsades de pointes in hemodynamically unstable patients, treat with electrical cardioversion. In stable patients, treat with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct electrolyte abnormalities. AVOID class Ia (quinidine, disopyramide, procainamide), class IC (flecainide, ecaicinide, propafenone), and most class III antidysrhythmics (N-acetylprocainamide, sotalol). 8. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. 9. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. 10. Treat dystonia with oral or intravenous diazepam, agitation with benzodiazepines, hyperthermia with sponge application of tepid water and fanning (AVOID phenothiazines), and severe hyperthermia with neuromuscular paralysis. (Meditext)

**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.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

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. Use of a designated area is recommended for handling of potent materials.

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

Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines
No exposure standards allocated.

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.

Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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
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. This material is corrosive. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Hand protection
Not available.

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 powder.

Physical state
Solid.

Form
Powder.

Odor
Odorless.

Odor threshold
Not available.

pH
1.5 - 2.5 (5% solution)

Melting point/freezing point
379.4 - 392 °F (193 - 200 °C) (decomposes)

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 Very soluble.
Partition coefficient (n-octanol/water) 2.58
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.

Other information
- Chemical family: Piperazine derivative.
- Molecular formula: C21H27ClN2O2 . 2HCl
- Molecular weight: 447.83
- Percent volatile: < 5%
- Solubility (other): Soluble in chloroform; slightly soluble in acetone; freely soluble in ethanol (96%); practically insoluble in ether.
- Specific gravity: 0.3

10. Stability and reactivity
- Reactivity: No reactivity hazards known.
- Chemical stability: Stable at normal conditions.
- Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
- Conditions to avoid: None under normal conditions.
- Incompatible materials: Strong oxidizing agents.
- Hazardous decomposition products: NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
- Ingestion: Causes digestive tract burns. Harmful if swallowed.
- Inhalation: May cause irritation to the respiratory system.
- Skin contact: Causes severe skin burns.
- Eye contact: Causes serious eye damage.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Cross sensitivity
- Persons sensitive to one of the antihistamines may be sensitive to this material also.

Medical conditions aggravated by exposure

Acute toxicity
- Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxyzine Hydrochloride (CAS 2192-20-3)</td>
<td>Oral LD50</td>
<td>Rat 950 mg/kg 690 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Causes severe skin burns and eye damage.
Serious eye damage/eye irritation: Causes serious eye damage.
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: Based on available data, the classification criteria are not met.

Mutagenicity
- S. typhimurium Ames assay
  - Result: Negative.
Carcinogenicity

Based on available data, the classification criteria are not met. Negative results in short-term animal studies and epidemiological studies. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Reprodutivity

25 mg/kg/day Reproductivity test
Result: No effects on fertility.
Species: Rat

5.5 mg/kg Reproductivity test
Result: High frequency of abortion.
Species: Pig

60 - 200 mg/kg Reproductivity test
Result: Increase in cleft palates and other defects were observed.
Species: Rat

Specific target organ toxicity - single exposure
May cause irritation to the respiratory system. Narcotic effects.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

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

12. Ecological information

Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations.

Local disposal regulations
Not available.

Hazardous waste code
D002: Waste Corrosive material [pH <=2 or =>12.5, or corrosive to steel]

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
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.
All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
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 This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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>Yes</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>Yes</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 Chemical Substances (EINECS)</td>
<td>Yes</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>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*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 05-08-2008
Revision date 02-01-2013
Version # 02
Further information Not available.

Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information

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