



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

ATTENTION !

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.

BIPERIDEN HYDROCHLORIDE

Catalog Number: 1073004

Revision Date:

August 17, 2009

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Biperiden Hydrochloride

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: Adverse effects of anticholinergic agents may include dry mouth, nose, throat, and skin; constipation; fast, pounding, or irregular heartbeat; blurred vision; enlarged pupils and increased sensitivity to light; difficult or reduced urination; decreased sweating; fever; dizziness; drowsiness; weakness; headache; speech disturbances; heartburn; and skin rash. This material may also cause sleep disturbances, dizziness when standing, and involuntary jerky body movements. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose of anticholinergic agents may cause the above adverse effects and incoordination; mood and mental changes (hallucinations, memory loss, confusion, agitation), flushing, nausea, vomiting, difficult swallowing, seizures, coma, and death.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart disease, hiatal hernia or other gastrointestinal tract disorders, bleeding disorders, glaucoma, myasthenia gravis, prostate enlargement or other urinary obstruction, kidney or liver impairment, hyperthyroidism, epilepsy, and hypertension.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

BIPERIDEN HYDROCHLORIDE

Catalog Number: 1073004

Revision Date:

August 17, 2009

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Biperiden Hydrochloride

Formula: C₂₁H₂₉NO . HCl

Synonym: n/f

Chemical Name: 1-Piperidinepropanol, alpha-bicyclo[2.2.1]hept-5-en-2-yl-alpha-phenyl-, hydrochloride

CAS: 1235-82-1

RTECS Number: TN3706000

Chemical Family: Piperidine derivative; tertiary amine

Therapeutic Category: Anticholinergic; antiparkinsonian

Composition: Pure material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation and toxicity. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of anticholinergic overdose should be symptomatic and supportive and may include the following:

1. Perform gastric lavage and administer activated charcoal as a slurry. Do not induce vomiting.
2. Maintain open airway and assist ventilation if needed.
3. Tachydysrhythmias may respond to physostigmine or IV beta-blockers.
4. Ventricular dysrhythmias may respond to IV sodium bicarbonate or lidocaine.
5. For seizures, administer intravenous benzodiazepine. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia.
6. Intravenous benzodiazepine may be used to control agitation. Physostigmine may also be used control agitation and delirium.
7. For severe hypertension, administer nitroprusside, labetalol, nitroglycerin, or phentolamine.
8. Manage hyperthermia with external cooling.
9. For rhabdomyolysis, administer 0.9% saline. Monitor input and output, electrolytes, CK, and renal function. Administer diuretics if needed to maintain urine output.
10. For hypotension, infuse 10 to 20 mL/kg isotonic fluid. If unresponsive, administer dopamine or norepinephrine. If hypotension is secondary to severe tachycardia, use esmolol to control tachycardia.
11. Hemodialysis, hemoperfusion, peritoneal dialysis, and repeat-dose charcoal will not effectively remove anticholinergic agents. [Meditext 2008; Poisoning and Drug Overdose, 4th edition]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

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

SECTION 6 - ACCIDENTAL RELEASE MEASURES

BIPERIDEN HYDROCHLORIDE

Catalog Number: 1073004

Revision Date:

August 17, 2009

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

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. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White crystalline powder; practically odorless.

Odor Threshold: n/f

pH: 5.0 - 6.5 (0.2% aqueous solution)

Melting Range: Approximately 275°C (decomposes); also reported as 238°C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Slightly soluble

Fat Solubility: n/f

Other Solubility: Slightly soluble in ether, in alcohol, and in chloroform; sparingly soluble in methanol; very slightly soluble in dichloromethane.

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

BIPERIDEN HYDROCHLORIDE**Catalog Number:** 1073004**Revision Date:**August 17, 2009

Explosive Properties: n/f**Oxidizing Properties:** n/f**Formula:** C₂₁H₂₉NO . HCl**Molecular Weight:** 347.92

BIPERIDEN HYDROCHLORIDE

Catalog Number: 1073004

Revision Date:

August 17, 2009

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Light and moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits very toxic fumes of NO_x and HCl. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50 : 750 mg/kg

Oral Mouse: LD50 : 530 mg/kg

Other Toxicity Data: Oral Dog LD50 : 340 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS # 214-976-2
Risk Phrase : R22

SECTION 16 - OTHER INFORMATION

Revision: 17-Aug-09

Previous Revision Date: 23-Dec-03