



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.

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DIPHENHYDRAMINE HYDROCHLORIDE

Catalog Number: 1218005

Revision Date:

July 1, 2007

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Diphenhydramine Hydrochloride

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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

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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

EMERGENCY OVERVIEW - Toxic.

Adverse Effects: Adverse effects may include drowsiness; dizziness; nausea or stomach pain; nervousness; difficulty swallowing; skin rash; unusual tiredness or weakness; fast, pounding, or irregular heartbeat; clay-colored stools or dark urine; fever; headache; visual disturbances; unusual excitement; restlessness or irritability; nightmares; and thickening of mucus. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects include clumsiness; severe drowsiness; fast or irregular heartbeat; shortness of breath; trouble sleeping; feeling faint; severe dryness of mouth, nose or throat; dilated pupils; hallucinations; seizures; coma; confusion; delirium; and psychoses.

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

Chronic: Possible hypersensitization, dental problems, and oral candidiasis.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, angle-closure glaucoma, enlarged prostate gland, porphyria, and urinary retention or bladder neck obstruction.

Cross Sensitivity: Persons sensitive to one antihistamine may be sensitive to this material also.

Target Organs: Central nervous system

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Diphenhydramine Hydrochloride

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Formula: C₁₇H₂₁NO . HCl

Synonym: n/f

Chemical Name: Ethanamine, 2-(diphenylmethoxy)-N,N-dimethyl-, hydrochloride

CAS: 147-24-0

RTECS Number: KR7000000

Chemical Family: Ethanolamine derivative

Therapeutic Category: Antihistaminic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation and pupil dilation. Avoid eye contact. Flush with copious quantities of water.

Skin: May cause irritation or contact dermatitis, and can be absorbed through the skin. Avoid contact. Flush with copious quantities of water.

Ingestion: May cause irritation, bitter taste, and toxicity. Avoid ingestion. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract. Its onset of action is within 1 hour and its duration of action is 6 to 8 hours.

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 overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first.
3. For QRS widening or ventricular tachycardia, administer sodium bicarbonate. Repeat as needed. Consider lidocaine, if sodium bicarbonate is not successful.
4. 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.
5. To distinguish anticholinergic delirium, administer physostigmine. Use CAUTION because it can precipitate seizures and dysrhythmias.
6. Hemodialysis and hemoperfusion are of no value. [Meditext 2007]

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

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 labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

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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: Industry: 200 micrograms/m³

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 or almost white crystalline powder; odorless

Odor Threshold: n/f

pH: About 5.5 (1% aqueous solution); also reported as 4.0 - 6.0 (5% aqueous solution)

Melting Range: 166 - 172° 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: Freely soluble

Fat Solubility: n/f

Other Solubility: Freely soluble in alcohol and in chloroform; sparingly soluble in acetone; very slightly soluble in benzene and in ether

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

Percent Volatile: 0.5

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₁₇H₂₁NO · HCl

Molecular Weight: 291.82

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light, which causes material to slowly darken.

Incompatibilities: Oxidizing agents and solutions of alkalis or strong acids.

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

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 500 mg/kg

Oral Mouse: LD50: 164 mg/kg

Other Toxicity Data: Guinea Pig LD50: 280 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: Male rats administered diphenhydramine hydrochloride at doses up to 635 ppm had a marginally increased incidence of uncommon brain neoplasms (astrocytomas or gliomas) and of aveolar/bronchiolar neoplasms, and female rats administered doses up to 313 ppm had a marginal increase in the incidence of pituitary gland adenomas. There was no evidence of carcinogenicity in male or female mice fed diets containing up to 313 ppm diphenhydramine hydrochloride.

Mutagenicity Data: Diphenhydramine hydrochloride tested negative in the *S. typhimurium* Ames assay, with and without activation. It did not induce trifluorothymidine (Tft) resistance in mouse L5178Y lymphoma cells, with or without activation. Diphenhydramine induced chromosomal aberrations at very high, toxic doses in Chinese hamster ovary cells, without activation but not with it, and did not induce sister chromatid exchanges, with or without activation.

Reproductive and Developmental Effects: Diphenhydramine may cause an increased level of uterine activity and its use in pregnant women may result in premature labor. Epidemiologic studies of children whose mothers used diphenhydramine during pregnancy have had mixed results. Studies in rats and rabbits at doses up to 5 times the human dose have not shown that diphenhydramine causes harm to the fetus or impaired fertility. One study found an increase in skeletal fragility in the fetuses of pregnant mice treated with 1.5 to 2.5 times the maximum human dose of diphenhydramine. Alterations in behavior occurred in the offspring of rats administered 3 times the human dose during pregnancy, but the frequency of malformations was not increased. The usual oral adult dose of diphenhydramine is 25 to 50 mg every 4 to 6 hours.

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

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Packing Group: n/f**Additional Transport Information:** n/f

SECTION 15 - REGULATORY INFORMATION
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U.S. Regulatory Information: n/f**International Regulatory Information:** EINECS # 205-687-2
Hazard Code: Xn
Risk Phrases: R22
Safety Phrases: S36

SECTION 16 - OTHER INFORMATION

Revision: 01-Jul-07**Previous Revision Date:** 05-May-03