



Material Safety Data Sheet

12601 Twinbrook Parkway
Rockville, MD 20852 USA

Telephone calls: (301) 881-0666
8:00am - 5:00pm EST Mon. - Fri.

Responsible Party: Roger Williams

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PSEUDOEPHEDRINE HYDROCHLORIDE

Catalog Number: 1581005

Package Size: 125 mg

Revision Date:

August 3, 2004

SECTION 1 - IDENTIFICATION

Common Name: Pseudoephedrine Hydrochloride **Formula:** C₁₀H₁₅NO . HCl

Synonym: d-Pseudoephedrine hydrochloride

Chemical Name: Benzenemethanol, alpha-[1-(methylamino)ethyl]-, [S- (R*,R*)]-, hydrochloride

CAS Number: 345-78-8

RTECS Number: UL5950000

Chemical Family: Phenethylamine derivative

Therapeutic Category: Adrenergic (vasoconstrictor)

SECTION 2 - INGREDIENT INFORMATION

<u>Principle Components</u>	<u>Percent</u>	<u>Exposure Limits</u>
Pseudoephedrine Hydrochloride	Pure Material	n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of pseudoephedrine hydrochloride is 60 mg every 4 to 6 hours, not to exceed a maximum of 240 mg in a twenty-four hour period.

Adverse Effects: Adverse effects may include nervousness, restlessness, trouble sleeping, dizziness, headache, difficult or painful urination, increased sweating, nausea or vomiting, trembling, fast or pounding heartbeat, and unusual paleness or weakness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Symptoms of acute or chronic overdose include convulsions; rapid breathing; hallucinations; increase in blood pressure; severe or continuing change in heartbeat; severe or continuing shortness of breath or troubled breathing; and unusual nervousness, restlessness or excitement.

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

Chronic: Possible hypersensitization.

Inhalation: May cause irritation. Remove to fresh air.

New Pig MSDS# (MSD-V215)

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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. Avoid ingestion. Flush out mouth with water. This material is rapidly absorbed from the gastrointestinal tract. Its onset of action occurs within 15 to 30 minutes and its duration of action is 3 to 4 hours.

Medical Conditions Aggravated by Exposure:

Hypersensitivity to material, severe coronary artery disease or hypertension, and treatment with MAO inhibitors.

Cross Sensitivity:

Persons sensitive to other sympathomimetics (e.g., albuterol, amphetamines, ephedrine, epinephrine, isoproterenol, metaproterenol, norepinephrine, phenylephrine, phenylpropanolamine, and terbutaline) may be sensitive to this material also.

Pregnancy Comments:

Pregnancy studies in humans have not been done, but studies in animals have not shown that pseudoephedrine causes birth defects. However, pseudoephedrine has caused reduced average weight, length, and rate of skeletal ossification in the animal fetus.

Pregnancy Category:

n/f

SECTION 4 - FIRST AID MEASURES

General:

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.

Overdose Treatment:

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

1. Induce vomiting and/or perform gastric lavage within four hours of overdose in order to be effective.
2. Activated charcoal is useful only if administered within one hour of overdose.
3. Forced diuresis will increase elimination of pseudoephedrine, provided renal function is adequate. However, diuresis is not recommended for severe overdosage.
4. Monitor cardiac function and serum electrolytes.
5. If there are signs of cardiac toxicity, intravenous propranolol may be indicated.
6. Hypokalemia may be treated, if necessary, with a slow infusion of dilute potassium chloride solution; serum potassium concentration should be monitored during and for several hours after administration of potassium chloride.
7. For delirium or convulsions, intravenous diazepam may be administered. [USP DI 2004]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: n/f

Oral Mouse: LD50: 371 mg/kg

Irritancy Data: n/f

Target Organ(s): n/f

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f

Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f

Lower Flammable Limit: n/f

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

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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 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to light.

Incompatibilities: Oxidizing agents, acids, acid chlorides, acid anhydrides.

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 8 - HANDLING / SPILL / DISPOSAL MEASURES

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.

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.

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

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

Ventilation: No special ventilation requirements.

Gloves: Rubber

Eye Protection: Safety Glasses

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White to off-white crystals or powder; odorless or faint characteristic odor.

Melting Point: 181 - 186° C

Solubility in Water: Freely soluble

Vapor Density: n/f

Boiling Point: n/f

Evaporation Rate: n/f

Specific Gravity: n/f

Reactivity in Water: n/f

Vapor Pressure: n/f

% Volatile by Volume: n/f