



Material Safety Data Sheet

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BUPRENORPHINE HYDROCHLORIDE

Catalog Number: 1078700

Package Size: 50 mg

Revision Date:

April 9, 2002

EMERGENCY OVERVIEW - Poison. WARNING: This material may cause prolonged respiratory depression. Avoid contact!

SECTION 1 - IDENTIFICATION

Common Name: Buprenorphine Hydrochloride

Formula: C₂₉H₄₁NO₄ . HCl

Synonym: n/f

Chemical Name: 6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-alpha-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-alpha-methyl-, hydrochloride, [5alpha, 7alpha (S)]-

CAS Number: 53152-21-9

RTECS Number: KM7758000

Chemical Family: Semisynthetic opioid

Therapeutic Category: Analgesic (narcotic)

SECTION 2 - INGREDIENT INFORMATION

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

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: Buprenorphine hydrochloride is given by intravenous or intramuscular injection in doses of 0.3 mg (base) every six hours. It may also be used orally (dissolved under the tongue) in doses of 0.2 to 0.4 mg (base) every 6 to 8 hours.

Adverse Effects: Adverse effects may include drowsiness, nausea, dizziness, headache, vomiting, sweating, drop in blood pressure and unusually slow breathing. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

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Overdose Effects: Symptoms of overdose include cold, clammy skin; confusion; convulsions; severe dizziness or drowsiness; low blood pressure; severe nervousness or restlessness; pinpoint pupils; slow heartbeat; severe weakness; slow or troubled breathing; and unconsciousness.

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

Chronic: Possible hypersensitization and potential for dependence or abuse.

Inhalation: May cause irritation and adverse effects. Avoid inhalation. Remove to fresh air.

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

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

Ingestion: May cause irritation. Flush out mouth with water. This material is absorbed from the mucous membranes of the mouth.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material, respiratory impairment or disease, active alcoholism, and inflammatory bowel disease.

Cross Sensitivity: n/f

Pregnancy Comments: Adequate and well-controlled pregnancy studies in humans have not been done. Some animal studies in rats and rabbits given high doses showed evidence of adverse effects on the fetus.

Pregnancy Category: C

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 buprenorphine overdose may include the following:

1. Use the opioid antagonist naltrexone for buprenorphine-induced respiratory depression. **WARNING:** Naltrexone may not be completely effective. The respiratory stimulant doxapram may be administered if naltrexone fails, and assisted or controlled ventilation may also be necessary.
2. Monitor respiratory and cardiac status of patient.
3. Administer intravenous fluids, vasopressors, and other supportive measures as needed.

[USP DI 2002; PDR 56th ed. 2002]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: >1 gram/kg

Oral Mouse: LD50: 800 mg/kg

Irritancy Data: n/f

Target Organ(s): Central nervous system; respiratory system

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 and excessive moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits 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. Additionally, because this is a controlled substance, notify local DEA office for appropriate disposal procedures.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Ventilation: Recommended.

Gloves: Rubber

Eye Protection: Safety Goggles

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 crystalline powder; odorless.

Melting Point: 265 - 271° C

Solubility in Water: Slightly 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