

# **Material Safety Data Sheet**

12601 Twinbrook Parkway Rockville, MD 20852 USA

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

**Revision Date:** 

April 9, 2002

**Responsible Party: Roger Williams** 

**ATTENTION !** 

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#### BUPRENORPHINE HYDROCHLORIDE

<b>Catalog Number:</b>	1078700	Package Size:	50 mg

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

# **SECTION 1 - IDENTIFICATION**

<b>Common Name:</b>	Buprenorphine Hydrochloride	Formula: C29H41NO4.HCl	
Synonym:	n/f		
Chemical Name:		7-(cyclopropylmethyl)-alpha-(1,1-dimethylethyl)-4,5-epoxy-18 methyl-, hydrochloride, [5alpha, 7alpha (S)]-	3,19-
CAS Number:	53152-21-9	RTECS Number: KM7758000	
<b>Chemical Family:</b>	Semisynthetic opioid		
Therapeutic Category:	Analgesic (narcotic)		
	SECTION 2 - INGR	EDIENT INFORMATION	
Principle Components	Perce	nt Exposure Limits	

Buprenorphine Hydrochloride

Pure Material

n/f

### **SECTION 3 - HEALTH HAZARD INFORMATION**

Buprenorphine hydrochloride is given by intravenous or intramuscular injection in doses of 0.3 mg (base) **Usual Adult Dose:** 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 may include drowsiness, nausea, dizziness, headache, vomiting, sweating, drop in blood **Adverse Effects:** pressure and unusually slow breathing. Possible allergic reaction to material if inhaled, ingested or in

contact with skin.

## BUPRENORPHINE HYDROCHLORIDE

Overdose Effects:       Symptoms of overdose include cold, clammy skin: confusion; convulsions; severe dizziness or drowsin is voo kood pressure; severe nervousness or readlessness, pinpoint pupils, slow hearbeat; severe weaken as one or trouble by experiment pressure in a conversion on a dverse effects. Avoid inhalation.         Avoite:       Possible type:resnsitization and potential for dependence or abuse.         Inhalation:       May cause irritation.         May cause irritation.       Fush with copious quantities of water.         Skin:       May cause irritation.         May cause irritation.       Fush with copious quantities of water.         Inhalation:       May cause irritation.         May cause irritation.       Fush out mouth with water. This material is absorbed from the mucous membran the mouth.         May cause irritation.       Fush out mouth with water. This material is absorbed from the mucous membran the mouth.         Magravated by Exposure:       Adequate and well-controlled pregnancy studies in humans have not been done. Some animal studies i and rabbits given high doses showed evidence of adverse effects on the feaus.         Pregnaney Comment:       Adequate and well-controlled pregnancy studies in humans have not been done. Some animal studies i respiratory fush intravenous fluks, vasopressons, effects.         Overdose Treatment:       If certains and societor controlled vertification must receive immediat methodical attention.         Overdose Treatment:       If certain reconos systerency immediate methodical attention.	Catalog Number: 1078700	) Pac	kage Size: 50 mg	<b>Revision Date:</b>	April 9, 2002
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Inhabition:       May cause irritation and adverse effects. Avoid inhalation. Remove to fresh air.         Eye:       May cause irritation. Avoid contact. Flush with copious quantities of water.         Ingestion:       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 membran the mouth.         Medical Condition:       May cause irritation. Flush out mouth with water. This material is absorbed from the mucous membran the mouth.         Mag cause irritation.       Inspection of the mutotic pregnancy studies in humans have not been done. Some animal studies i and rabbits given high doses showed evidence of adverse effects on the fetus.         Pregnancy Comment:       Adequate and well-controlled pregnancy studies in humans have not been done. Some animal studies i 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 (anaphylacity creations must receive immediate medical attention.         Overdose Treatment:       Treatment of bupernorphine overdose may include the following:         1. Use the opioid antagonist nathrexone fits bupernorphine-induced respiratory depression. WARNIN Nathrexone may not be completely effective. The respiratory stimulant doxaparam may be administere nathrexone fitski, susporespisatory and cardia status of patient.	Acute:	Possible e	eye, skin, gastrointestinal and/or re	espiratory tract irritation.	
Eye:       May cause irritation. Flush with copious quantities of water.         Skin:       May cause irritation. Avoid contact. Flush with copious quantities of water.         Ingestio:       May cause irritation. Plush out mouth with water. This material is absorbed from the mucous membran the mouth.         Medical Conditions       Hypersensitivity to the material, respiratory impairment or disease, active alcoholism, and inflammator bowed disease.         Cross Sensitivity:       n/f         Pregnancy Comments:       Adequate and well-controlled pregnancy studies in humans have not been done. Some animal studies i 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.         Overdlose Treatment:       Treatment of buprenorphine overdose may include the following:         1. Use the opioid antagonist naltrexone for buprenorphine-induced respiratory depression. WARNIN Naltrexone may to be completely effective. The respiratory istimulat doxapra may be administered naltrexone fails, and assisted or controlled ventilation may also be necessary.         2. Monitor respiratory and cardiae 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         <	Chronic:	Possible ł	hypersensitization and potential fo	r dependence or abuse.	
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	Flash Poir	nt: n/f			
Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materia	Auto-Ignition Temperatur	re: n/f		Lower Flammable Limit: n/f	
	Extinguisher Med	ia: Wate	r spray, dry chemical, carbon diox	kide or foam as appropriate for surrounding	g fire and materials.

# BUPRENORPHINE HYDROCHLORIDE Catalog Number: 1078700 Package Size: 50 mg Revision Date: April 9, 2002 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**

<b>Conditions to Avoid:</b>	Avoid exposure to light and excessive moisture.
Incompatibilities:	n/f
Decomposition Products:	When heated to decomposition material emits toxic fumes of NOx and HCl. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization?

#### 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.

No

- **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**

<b>Respiratory Protection:</b>	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.	
<b>Melting Point:</b>	265 - 271° C	
Solubility in Water:	Slightly soluble	Vapor Density: n/f
<b>Boiling Point:</b>	n/f	<b>Evaporation Rate:</b> n/f
Specific Gravity:	n/f	Reactivity in Water: n/f
Vapor Pressure:	n/f	% Volatile by Volume: n/f