



MATERIAL SAFETY DATA SHEET

Product Name: Buprenorphine Hydrochloride Injection 

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name
And Address** Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

**Emergency Telephone
Hospira, Inc.** CHEMTREC: 800 424-9300
224 212-2055

Product Name Buprenorphine Hydrochloride Injection

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Buprenorphine Hydrochloride
Chemical Formula $C_{29}H_{42}ClNO_4$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Buprenorphine Hydrochloride	0.03	53152-21-9	KM7758000
Water	99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used as a narcotic analgesic to treat pain. Target organs include the nervous system, respiratory system, eyes, gastrointestinal tract, cardiovascular system, and fetus.

**Occupational Exposure
Potential** Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact with solution.

Signs and Symptoms No signs or symptoms from occupational exposure are known. Clinical data suggests the following: sedation, nausea, dizziness/vertigo, sweating, headache, hypotension, vomiting, hypoventilation, miosis, confusion, blurred vision, euphoria, weakness, fatigue, dry mouth, nervousness, depression, slurred speech, paresthesia, altered heart rate, constipation, dyspnea, cyanosis, pruritis, diplopia and visual abnormalities.

**Medical Conditions
Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Data suggest asthma, head injury, liver dysfunction, renal dysfunction, pre-existing central nervous system, ocular and gastrointestinal ailments.

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4. FIRST AID MEASURES

Eye Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability:	Non-flammable
Fire & Explosion Hazard:	None
Extinguishing Media:	Use extinguishing media appropriate for the underlying cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	Protect from light by retaining in carton until contents have been used.
Storage	No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).
Special Precautions	Protect from freezing, light and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Buprenorphine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 0.3 mcg/m3 STEL: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless to slightly yellow liquid
Odor	Not Determined
Boiling Point	Not Determined
Freezing Point	Not Determined
Vapor Pressure	Not Determined
Vapor Density (Air=1)	Not Determined
Evaporation Rate	Not Determined
Bulk Density	Not Determined
Specific Gravity	Not Determined
Solubility	Soluble in water and dextrose solutions
pH	3.5 – 5.5

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	None
Hazardous Decomposition Products	Oxides of carbon, nitrogen and chlorine.
Hazardous Polymerization	None

11. TOXICOLOGICAL INFORMATION:**Acute Toxicity:**

Ingredient(s)	Percent	Test Type	Value	Units	Species
Buprenorphine Hydrochloride	100	LD50	260 >1000	mg/kg	Rats Mice

LD50 is the oral dosage that produces 50% mortality.

Product contains approximately 0.03% Buprenorphine Hydrochloride.

Mutagenicity	Not Determined
Target Organ Effects	In clinical use target organ effects include the nervous system, respiration, eyes, gastrointestinal tract and cardiovascular system.

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12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Determined.

13. DISPOSAL CONSIDERATIONS:

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Not Regulated
CERCLA Status	Not Regulated
SARA Status	Not Regulated
RCRA Status	Not Regulated
PROP 65 (Calif.)	Not Regulated

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator T. Straits MPH, CIH
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