



MATERIAL SAFETY DATA SHEET

Product Name: Nalbuphine Hydrochloride Injection, USP

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 Nalbuphine Hydrochloride Injection, USP

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name
Chemical Formula** Nalbuphine Hydrochloride

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Nalbuphine Hydrochloride	1 - 2	23277-43-2	QD3181000
Water	98 - 99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used to relieve pain. Possible target organs include the central nervous system, lungs, eyes and cardiovascular system.

**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.

Signs and Symptoms No signs or symptoms from occupational exposure are known. Clinical data suggest the following: nausea, vomiting, hallucinations, dizziness, vertigo, dry mouth, pinpoint pupils, headaches, restlessness, itching, respiratory depression.

**Medical Conditions
Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: central nervous system, respiratory system, gastrointestinal system.

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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 primary 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 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
Nalbuphine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 10 mcg/m ³ 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 liquid
Odor	None
Boiling Point	Approximately that of water (100 °C, 212 °F).
Freezing Point	Approximately that of water (0 °C, 32 °F).
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C).
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	1.0051-1.0071
Solubility	Aqueous solution
pH	3.0 – 4.5

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	Alkalies, tannic acid, iodic acid, potassium permanganate, borax, chlorates, ferric chloride, iodides, lead acetate, magnesia, mercury bichloride.
Hazardous Decomposition Products	Toxic fumes of nitrogen and sulfur oxides
Hazardous Polymerization	Not Determined.

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

Ingredient(s)	Percent	Test Type	Value	Units	Species
Nalbuphine Hydrochloride	100	LD50	1100	mg/kg	Dogs

LD50 is the dosage producing 50% mortality.

Product contains between approximately 1-2% Nalbuphine Hydrochloride.

Mutagenicity	Not Determined
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Target Organ Effects	In clinical use target organ effects include central nervous system, respiratory system, fetus, gastrointestinal tract.
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12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Available

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	Global Occupational Toxicology
Date Prepared	September 15, 2005
Date Revised	October 21 2008

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