



MATERIAL SAFETY DATA SHEET

Product Name: Bupivacaine Hydrochloride Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Note: Hospira, formerly the Hospital Products Division of Abbott Laboratories, was created as an independent company in May 2004.

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

Product Name Bupivacaine Hydrochloride Injection, USP

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Bupivacaine Hydrochloride
Chemical Formula $C_{18}H_{29}ClN_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Bupivacaine Hydrochloride	0.25-0.75	14252-80-3	TK6125000
Water	99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used as a local anesthetic that produces anesthesia by blockage of nerve conduction. Target organs include the central nervous system and heart.

**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: numbness, restlessness, anxiety, dizziness, ringing in the ear, visual impairment, tremor, convulsions, decreased blood pressure, slow heart rate, cardiac changes, cardiac arrest.

**Medical Conditions
Aggravated by Exposure** Data suggest pre-existing ailments in the following organs: central nervous system and cardiovascular system. Hypersensitivity to the material and/or similar materials.

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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	No special handling required.
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 and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Bupivacaine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 50 mcg/m ³ STEL: 500 mcg/m ³

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 Applicable

Specific Gravity Approximately that of water (1.0).

Solubility Soluble in water, dextrose solutions, alcohol

pH 4.0 – 6.5

10. STABILITY AND REACTIVITY

Chemical Stability Stable under standard use and storage conditions.

Incompatibilities None

Hazardous Decomposition Products Oxides of carbon and nitrogen

Hazardous Polymerization None

11. TOXICOLOGICAL INFORMATION:

Toxicity

Ingredient(s)	Percent	Test Type	Value	Units	Species
Bupivacaine Hydrochloride	100	LD50	18	mg/kg	Rabbits

LD50 is the dosage producing 50% mortality.
Product contains less than 1% Bupivacaine Hydrochloride.

Mutagenicity Not Determined.

Target Organ Effects In clinical use target organ effects include central nervous system and heart.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not determined.

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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	Bupivacaine Hydrochloride is not listed on the TSCA inventory.
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
Date Prepared	September 15, 2005

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