



## MATERIAL SAFETY DATA SHEET

**Product Name: Bupivacaine Hydrochloride and Epinephrine 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 and Epinephrine Injection , USP

**Synonyms** None

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name** Bupivacaine Hydrochloride and Epinephrine  
**Chemical Formula**

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Bupivacaine Hydrochloride	0.25-0.75	14252-80-3	TK6125000
Epinephrine	0.0005	51-43-4	DO2625000
Water	99	7732-18-5	ZC0110000

### 3. HAZARD INFORMATION

**Emergency Overview** In clinical use, this material is used to cause local or regional anesthesia or analgesia for surgical procedures. Bupivacaine hydrochloride is considered to be highly toxic by ingestion. Epinephrine is a potent drug and is considered to be highly toxic by ingestion and by skin contact. Target organs include the skin, nervous system, central nervous system, cardiovascular system and respiratory 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 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, mood 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.

**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). Protect from light.

**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/m3 STEL 500 mcg/m3
Epinephrine	8 hr TWA: Not Established	8 hr TWA Not Established	8 hr TWA: 1 mcg/m3 STEL: 20 mcg/m3

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**                                1.004 gm/L at 25°C.
- Solubility**                                        Aqueous solution
- 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 NOx
- Hazardous Polymerization**                              None

**11. TOXICOLOGICAL INFORMATION:**

**Toxicity**

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Bupivacaine Hydrochloride	100	LD50	18	mg/kg	Rabbits
Epinephrine	100	LD50	24-50	mg/kg	Rats, Mice

LD50 is the dosage producing 50% mortality.  
Product contains less than 1% Bupivacaine Hydrochloride and less than 0.001% Epinephrine.

- Mutagenicity**                                      Not determined.
- Target Organ Effects**                              Bupivacaine hydrochloride is a local anesthetic that produces anesthesia (numbness) by blockage of nerve conduction and can also adversely affect the central nervous system and heart. Produced decreased survival in rat pups and fetal death in rabbits at 5 and 9 times the maximum recommended daily dose, respectively, and has the potential to produce fetal toxicity in humans.

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**Target Organ Effects  
(continued)**

Epinephrine is a naturally occurring sympathomimetic amine that stimulates the sympathetic nervous system. Can produce irritation, pigment deposition, a reduction of intraocular pressure and a reduction in visual acuity to the eyes. Intranasal use can lead to rebound congestion while injection can lead to tissue necrosis due to local constriction of blood vessels. Use of epinephrine by pregnant women may delay labor by retarding uterine contractions and cause fetal anoxia. Has produced teratogenic effects in animals at 25 times the clinical dose and some mutagenic effect in bioassays. Nasal changes were produced by epinephrine hydrochloride in long-term inhalation studies in rats and mice at concentrations of 1.5 mg/m<sup>3</sup> or more.

**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** Bupivacaine Hydrochloride and Epinephrine are 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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