

## MATERIAL SAFETY DATA SHEET

**Product Name: Bupivacaine Hydrochloride Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

**Emergency Telephone**      CHEMTREC: North America: 800-424-9300;  
 International 1-703-527-3887; Australia (02) 8014 4880

**Hospira, Inc., Non-Emergency**      224-212-2000

**Product Name**      Marcaine Bupivacaine Hydrochloride Injection

**Synonyms**      2-Piperidinecarboxamide, 1-butyl-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name**      Bupivacaine Hydrochloride Monohydrate

**Chemical Formula**      C<sub>18</sub>H<sub>28</sub>N<sub>2</sub>O • HCl • H<sub>2</sub>O

**Preparation**      Non-hazardous ingredients include Water for Injection and may include dextrose. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH. Multiple-dose vials contain 0.1% of methylparaben added as preservative.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Bupivacaine Hydrochloride Monohydrate	≤0.75	14252-80-3	TK6125000

### 3. HAZARD INFORMATION

**Carcinogen List**

Substance	IARC	NTP	OSHA
Bupivacaine Hydrochloride Monohydrate	Not Listed	Not Listed	Not Listed

**Emergency Overview**      MARCAINE - Bupivacaine Hydrochloride Injection is a solution containing bupivacaine hydrochloride, a local anesthetic used for pain management. In clinical use, this material is indicated for local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system, respiratory system, and cardiovascular system.

**Occupational Exposure Potential**      Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that similar local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms**      Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion

may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

**Medical Conditions Aggravated by Exposure** Pre-existing hypersensitivity to bupivacaine or related amide-type anesthetics. Pre-existing nervous system or cardiovascular ailments.

**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** None anticipated from this aqueous product.
- Fire & Explosion Hazard** None anticipated from this aqueous product.
- Extinguishing media** As with any fire, 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** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

**7. HANDLING AND STORAGE**

- Handling** No special handling required for hazard control under conditions of normal product use.
- Storage** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
- Special Precautions** No special precautions required for hazard control.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Type	Exposure limits			
		mg/m <sup>3</sup>	ppm	µg/m <sup>3</sup>	Note
Bupivacaine Hydrochloride Monohydrate	Hospira EEL	N/A	N/A	50	
Bupivacaine Hydrochloride Monohydrate	Hospira STEL	N/A	N/A	500	

- Respiratory protection** Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
- Skin protection** If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
- Eye protection** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
- Engineering Controls** Engineering controls are normally not needed during the normal use of this product.

**9. PHYSICAL/CHEMICAL PROPERTIES**

- Appearance/Physical State** Liquid
- Color** Clear, Colorless
- Odor** Not determined
- Odor Threshold:** NA
- pH:** Between 4 and 6.5
- Melting point/Freezing point:** NA
- Initial Boiling Point/Boiling Point Range:** NA
- Evaporation Rate:** NA
- Flammability (solid, gas):** NA

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<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure:</b>	NA
<b>Vapor Density:</b>	NA
<b>Specific Gravity:</b>	NA
<b>Solubility:</b>	95 percent in ethanol, soluble in water
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature:</b>	NA
<b>Decomposition temperature:</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to avoid</b>	Not determined.
<b>Incompatibilities</b>	Strongly alkaline conditions. Methyl vinyl ether; zinc.
<b>Hazardous decomposition products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

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

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Bupivacaine Hydrochloride	100	LD50	Oral	18	mg/kg	Rabbit
Bupivacaine Hydrochloride	100	LD50	Intravenous	6	mg/kg	Rat
				6.1	mg/kg	Mouse
				3.4	mg/kg	Rabbit

<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and

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numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product

**Reproductive Effects** Decreased pup survival in rats and an embryocidal effect in rabbits have been observed when bupivacaine hydrochloride was administered to these species in doses comparable to nine and five times respectively the maximum recommended daily human dose (400 mg).

**Mutagenicity** The mutagenic potential of this product has not been evaluated.

**Carcinogenicity** Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including bupivacaine, have not been conducted.

**Target Organ Effects** Possible target organs include the nervous system, respiratory system, and cardiovascular system.

**12. ECOLOGICAL INFORMATION**

**Aquatic Toxicity** Not determined for product.

**Persistence/Biodegradability** Not determined for product.

**Bioaccumulation** Not determined for product

**Mobility in Soil** Not determined for product.

**13. DISPOSAL CONSIDERATIONS**

**Waste Disposal** All waste materials must be properly characterized. Further, disposal of all pharmaceuticals 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**

**ADR/ADG/ DOT STATUS:** Not regulated

**IMDG STATUS:** Not regulated

**ICAO/IATA STATUS:** Not regulated

**Transport Comments:** None

**15. REGULATORY INFORMATION**

**USA Regulations**

<b>Substance</b>	<b>TSCA Status</b>	<b>CERCLA Status</b>	<b>SARA 302 Status</b>	<b>SARA 313 Status</b>	<b>PROP 65 Status</b>
Bupivacaine Hydrochloride Monohydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

**RCRA Status** Not Listed  
**U.S. OSHA Classification** Target Organ Toxin  
 Possible Irritant

**GHS Classification** \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class** Not Applicable

**Hazard Category** Not Applicable

**Signal Word** Not Applicable

**Symbol** Not Applicable

**Prevention** P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement** Not Applicable

**Response:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling  
  
 Get medical attention if you feel unwell.

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Bupivacaine Hydrochloride Monohydrate

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** Not Applicable

**Safety Phrases:** Not Applicable

**16. OTHER INFORMATION:**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

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