1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name: Hospira, Inc.
Address: 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: CHEMTREC: 800 424-9300
Hospira, Inc.: 224 212-2055

Product Name: Bupivacaine Hydrochloride Injection, USP
Synonyms: None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name: Bupivacaine Hydrochloride
Chemical Formula: \(\text{C}_{18}\text{H}_{29}\text{ClN}_{2}\text{O}\)

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>0.25-0.75</td>
<td>14252-80-3</td>
<td>TK6125000</td>
</tr>
<tr>
<td>Water</td>
<td>99</td>
<td>7732-18-5</td>
<td>ZC0110000</td>
</tr>
</tbody>
</table>

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.
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).

**Special Precautions** Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OSHA-PEL</td>
</tr>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>8 hr TWA: Not Established</td>
</tr>
</tbody>
</table>

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

**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

<table>
<thead>
<tr>
<th>Appearance/Physical</th>
<th>Clear liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td>None</td>
</tr>
<tr>
<td>Odor</td>
<td>None</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Approximately that of water (100 °C, 212 °F).</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>Approximately that of water (0°C, 32 °F).</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Approximately that of water (17.5 mm Hg at 20 °C).</td>
</tr>
<tr>
<td>Vapor Density (Air=1)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Bulk Density</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water, dextrose solutions, alcohol</td>
</tr>
<tr>
<td>pH</td>
<td>4.0 – 6.5</td>
</tr>
</tbody>
</table>

## 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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>18</td>
<td>mg/kg</td>
<td>Rabbits</td>
</tr>
</tbody>
</table>

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.
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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