1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Hospital Products Division
200 Abbott Park Rd.
Abbott Park, Illinois 60064 - 6148

Customer Service Telephone: HPD : 1-800-222-6883
Emergency Telephone: CHEMTREC: 1-800-424-9300

Product Name: Bupivacaine Hydrochloride Injection, USP
Product Use: Anesthesia and analgesia.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>AIHA WEEL</th>
<th>Abbott EEL</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>0.25-0.75</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Applicable</td>
<td>0.05 mg/m3 TWA; 0.5 mg/m3 STEL</td>
<td>None</td>
</tr>
<tr>
<td>14252-80-3</td>
<td></td>
<td></td>
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<td></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. 
AIHA WEEL: American Industrial Hygiene Association - Workplace Environment Exposure Level. 
Abbott EEL: Abbott Laboratories Employee Exposure Limit. 
TWA: 8-hour Time Weighted Average. 
STEL: 15-minute Short Term Exposure Limit. 
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:
Clear liquid.
Odorless.
Highly toxic by ingestion.

ROUTES OF EXPOSURE
Oral: Unlikely
Dermal: Unlikely
Inhalation: Unlikely

HAZARD INFORMATION

Ingestion Rating: Highly Toxic
Skin Absorption Rating: Not determined.
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Central Nervous System • Skin • Cardiovascular System • Respiratory System

CARCINOGENICITY RATING:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>OSHA:</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>0.25-0.75</td>
<td>Not Listed</td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

NFPA RATING: Health: 3 Fire: 0 Reactivity: 0

SIGN AND SYMPTOMS: 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 any preexisting ailments in the following organs: central nervous system, 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. Seek immediate medical attention. Provide symptomatic/supportive care as necessary.

Notes To Physician: Monitor cardiovascular system function
5. FIRE FIGHTING MEASURES

FLAMMABILITY:
Flash Point (°C): Not applicable.
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.
Special Protective Equipment: Wear protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Dispose of material as directed in Section 13.

Personal Precautions: Wear appropriate protective clothing and equipment to prevent skin and eye contact.
Environment Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Protect from freezing.
Special Precautions: Protect from freezing.

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.
Respiratory Protection: Respiratory protection is not needed during normal product use.
Eyes: Eye protection not required during typical product use conditions. Recommended if eye contact is likely.
Gloves: If skin contact is anticipated: Neoprene or vinyl gloves are recommended.
Other Personal Protection Data: Not determined.
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear liquid.
Odor: Not determined.
Boiling Point @ 760 mm Hg (°C): Not determined. Water, approximately
Melting/Freezing Point (°C): Not determined. Water, approximately
Vapor Pressure (mm Hg): Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Soluble in: water, dextrose solutions, alcohol.
Specific Gravity: Not determined. Water, approximately.
pH: 4.0 - 6.5

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.
Self-Heating Tendency: Not determined.
Materials to Avoid: Not determined.
Hazardous Decomposition Products: When heated to decomposition it emits toxic fumes of : NOx.
Hazardous Polymerization: Not determined.
Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY - ORAL  
Data for component (s) given below.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride</td>
<td>0.25-0.75</td>
<td>LD50 =</td>
<td>18</td>
<td>mg/kg</td>
<td>Rabbits</td>
</tr>
<tr>
<td>14252-80-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACUTE TOXICITY - DERMAL  
Not determined.

ACUTE INHALATION  
Not determined.

CORROSIVITY:  
Not determined.

DERMAL IRRITATION:  
Not determined.
EYE IRRITATION: Not determined.

SENSITIZATION: Not determined.

TARGET ORGAN EFFECTS: In clinical use target organ effects include: central nervous system, heart.

REPRODUCTIVE EFFECTS: Active Ingredient : In animal and human data, adverse reproductive effects included : fetal toxicity.

CARCINOGENICITY: Not determined.

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

AQUATIC TOXICITY: Not determined.

BIODEGRADATION: Not determined.

GENERAL NOTES: Not determined.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Disposal should be made in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT:
Status: Not Regulated

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated

TDG (Canada)
Status: Not Regulated.
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>SARA 313 Information</th>
<th>Percent</th>
<th>SARA 313 Chemical</th>
<th>SARA EHS RQ (lbs)</th>
<th>SARA Extremely Hazardous RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupivacaine Hydrochloride [14252-80-3]</td>
<td>0.25-0.75</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

SARA 311/312 Hazard Categories:

Immediate Health: Not determined.
Delayed Health: Not determined.
Fire: Not determined.
Sudden Pressure: Not determined.
Reactivity: Not determined.

TSCA Inventory Status: Not determined.
CERCLA Status: Not determined.
RCRA Status: Not determined.

EPA FIFRA Classification: Toxicity Category I

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

Category of Danger: Harmful

Indication of Danger: Xn Harmful.

Risk Phrases: R22 Harmful if swallowed.

Safety Phrases:
S2 Keep out of reach of children.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S7 Keep container tightly closed.
S16 Keep away from sources of ignition - No Smoking.
S25 Avoid contact with eyes.
S24 Avoid contact with skin.
S13 Keep away from food, drink, and animal feeding stuffs.
S52 Not recommended for interior use on large surface areas.
ICH CLASSIFICATION:  
Class 2 - Serious Hazard.

CANADIAN REGULATIONS:

Canadian Inventory:  All ingredients comply with the Canadian Domestic Substances List
WHMIS Hazard Class:  D1A  VERY TOXIC MATERIALS

Notes:
1. SARA = Superfund Amendments and the Reauthorization Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
7. ICH = International Committee for Harmonization.

16. OTHER INFORMATION

Document Authored By:  Dan L. Furlan
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