

Product Name: Bupivacaine Hydrochloride Injection, USP
Issued: 08/07/2000



MATERIAL SAFETY DATA SHEET

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.
List Number: 4272: 5749: 5748: 4274: 4273: 5622: 5623: 5756: 5757: 5758: 1158: 1159: 1160:
1161: 1162: 1163: 1164: 1165: 5747: 3481: 3613: 3479: 3480

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Bupivacaine Hydrochloride 14252-80-3	0.25-0.75	Not Listed	Not Listed	Not Applicable	0.05 mg/m3 TWA; 0.5 mg/m3 STEL	None

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 Environmental 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

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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:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Bupivacaine Hydrochloride 14252-80-3	0.25-0.75	Not Listed	Not Listed	Not Listed	Not Listed

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

SIGNS 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.
Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Protect from freezing.
Storage : Store at controlled room temperature of 15-30 deg. C (59-86 deg. F).
Special Precautions: Protect from freezing.

8. EXPOSURE CONTROLS/PERSONAL 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
Viscosity (centipoise): Not determined. Water, approximately.

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.

Ingredients	Percent	Acute Test	Value	Units	Species
Bupivacaine Hydrochloride 14252-80-3	0.25-0.75	LD50 =	18	mg/kg	Rabbits

ACUTE TOXICITY - DERMAL Not determined.
ACUTE INHALATION Not determined.
CORROSIVITY: Not determined.
DERMAL IRRITATION: Not determined.

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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

SARA 313 Information	Percent	SARA 313 Chemical:	SARA EHS RQ (lbs):	SARA Extremely Hazardous RQ (lbs):
Ingredients Bupivacaine Hydrochloride 14252-80-3	0.25-0.75	No	Not Applicable	Not applicable

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.

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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 Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. ICH = International Committee for Harmonization.

16. OTHER INFORMATION

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