

~~BUPIVACAINE HYDROCHLORIDE INJECTION, USP~~~~Abbott~~

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

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
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
Skin Notation: 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

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 (deg C): Not applicable.

Autoignition Temp, (deg 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 detennined.

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 (deg C): Not determined. Water, approximately

Melting/Freezing Point (deg C): Not determined. Water, approximately

Vapor Pressure (mm Hg): Not determined.

Bulk Density at 20 deg 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	LD50=	18	mg/kg	Rabbits

14252-80-3
0.25-0.75

 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

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

 SARA 311/312 Hazard Catagories:

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 Pictogram(s):

D1A VERY TOXIC MATERIALS

Class D - Poisonous and Infectious Material, Division 1 - Material Causing Immediate and Serious and Toxic Effects, Subdivision A - Very Toxic Material

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, 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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