

MATERIAL SAFETY DATA SHEET PAGE 1
Marcaine with Epinephrine for Injection, USP
ISSUED 08/19/11

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: Marcaine with Epinephrine for Injection, USP
List Number: 1746, 1749, 1750, 1752, 1755
MANUFACTURER: Hospital Products Division
Abbott Laboratories
Abbott Park, Illinois 60064
EMERGENCY TELEPHONE NUMBER: 1-847-937-7970
CHEMTREC TELEPHONE NUMBER: 1-800-424-9300
2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME: Epinephrine *
CAS/RTECS NUMBERS: 51-43-3 / DO2625000
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: 1 mcg/m³, skin, eye (Abbott Laboratories)
LIMITS STEL: 20 mcg/m³ **
CEILING: N/A
* Hazardous per OSHA criteria
**Up to four excursions allowed, no closer than 1 hour apart, so long as the 8-hour TWA is maintained.
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2. COMPOSITION/INFORMATION ON INGREDIENTS, continued

INGREDIENT NAME: Bupivacaine Hydrochloride *
CAS/RTECS NUMBERS: 14252-80-3/TK6125000
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: 0.05 mg/m³ (Abbott Laboratories)

LIMITS STEL: 0.5 mg/m³

CEILING: N/A

* Hazardous per OSHA criteria

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: In clinical use, this material is used to cause

local or regional anesthesia or analgesia for surgical procedures.

Bupivacaine hydrochloride is considered to be highly toxic by ingestion. Epinephrine is a potent drug and is considered to be highly toxic by ingestion and by skin contact. Target organs include the skin, nervous system, central nervous system, cardiovascular system and respiratory system.

ROUTE(S) OF ENTRY: Skin: Unlikely

Inhalation: Unlikely

Ingestion: Unlikely

INGESTION RATING: Possibly highly toxic

SKIN ABSORPTION RATING: Possibly highly toxic

INHALATION RATING: N/D

CORROSIVENESS RATING: N/D

SKIN CONTACT RATING: N/D

SKIN SENSITIZATION RATING: N/D

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3. HAZARDS INFORMATION, continued

EYE CONTACT RATING: N/D

TARGET ORGANS: Skin, nervous system, central nervous system, cardiovascular system, respiratory system

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L

ACGIH: N/L

None

SIGNS AND SYMPTOMS: N/D. In clinical use, effects include numbness,

excitation/depression, restlessness, anxiety, dizziness, tinnitus,

blurred vision, tremors, convulsions, hypotension, bradycardia, ventricular arrhythmias, heart block, and cardiac arrest.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. Data for bupivacaine

hydrochloride suggest pre-existing central nervous system or cardiovascular ailments. Hypersensitivity to amide-type local anesthetics, to sympathomimetic amines or to bisulfites.

4. FIRST AID MEASURES

EYES: Remove from source of exposure. Flush with copious amounts of

water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, maintaining ventilation, controlling convulsions, and monitoring cardiovascular function, as necessary.

SKIN: Remove from source of exposure. Flush with copious amounts of

water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, maintaining ventilation, controlling convulsions, and monitoring cardiovascular function, as necessary.

INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, maintaining ventilation, controlling convulsions, and monitoring cardiovascular function, as necessary.

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4. FIRST AID MEASURES, continued

INHALATION: Remove from source of exposure. If signs of toxicity occur,

seek medical attention. No known antidote. Provide symptomatic/supportive care, maintaining ventilation, controlling convulsions, and monitoring cardiovascular function, as necessary.

5. FIRE FIGHTING PROCEDURES

FLASH POINT: Non-flammable

FLASH POINT METHOD: N/A

LOWER EXPLOSIVE LIMIT(%): N/D

UPPER EXPLOSIVE LIMIT(%): N/D

AUTOIGNITION TEMPERATURE: N/A

FIRE & EXPLOSION HAZARDS: N/D

EXTINGUISHING MEDIA: Use media appropriate for primary cause of fire.

FIRE FIGHTING INSTRUCTIONS: Fire fighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

6. ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: Absorb with suitable material and place into container for disposal in accordance with Section 13.

7. HANDLING AND STORAGE

HANDLING: Protect from light.

STORAGE: Store at controlled room temperature between 15-30 deg. C

(59-86 deg. F).

SPECIAL PRECAUTIONS: Protect from light.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: No special provisions are required under normal product use.

RESPIRATORY PROTECTION: Not needed during normal product use.

SKIN PROTECTION: If skin contact is likely, impervious gloves are recommended.

EYE PROTECTION: Not required under typical product use conditions. Eye

protection is recommended if eye contact is likely.

OTHER PROTECTION: N/D

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Clear, colorless solution.

ODOR: N/D

BOILING POINT: Water (approx.)

MELTING/FREEZING POINT: Water (approx.)

VAPOR PRESSURE (mm Hg): N/D

VAPOR DENSITY (Air=1): N/D

EVAPORATION RATE: N/D

BULK DENSITY: 1.004 - 1.007 g/mL

SPECIFIC GRAVITY: Water (approx.)

SOLUBILITY: Highly soluble in water.

pH: 3.4 - 4.5

VISCOSITY: N/D

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.

INCOMPATIBILITIES: N/D

HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition it emits

toxic fumes of NO_x.

HAZARDOUS POLYMERIZATION: N/D

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11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD₅₀ = 18 mg/kg in rabbits for bupivacaine hydrochloride (Highly Toxic). LD₅₀ = 24-50 mg/kg in mice and rats

for epinephrine (Highly Toxic).

DERMAL TOXICITY: N/D. Convulsions reported following dermal application to the scalp of 750 mg for bupivacaine hydrochloride.

LD₅₀ = 62 mg/kg in rats for epinephrine (Highly Toxic).

INHALATION TOXICITY: N/D. LD₅₀ (intratracheal) = 11 mg/kg in rabbits

for bupivacaine hydrochloride. Clinical effects produced by oral/inhalation administration of 0.16 mg or more for epinephrine.

CORROSIVENESS: N/D

DERMAL IRRITATION: N/D

OCULAR IRRITATION: N/D

DERMAL SENSITIZATION: N/D

SPECIAL TARGET ORGAN EFFECTS: N/D. Bupivacaine hydrochloride is a

local anesthetic that produces anesthesia (numbness) by blockage of

nerve conduction and can also adversely effect the central nervous

system and heart. Produced decreased survival in rat pups and fetal

death in rabbits at 5 and 9 times the maximum recommended daily dose, respectively, and has the potential to produce fetal toxicity

in humans. Epinephrine is a naturally occurring sympathomimetic

amine that stimulates the sympathetic nervous system. Can produce irritation, pigment deposition, a reduction of intraocular pressure and a reduction in visual acuity to the eyes. Intranasal use can lead to rebound congestion while injection can lead to tissue necrosis due to local constriction of blood vessels. Use of epinephrine by pregnant women may delay labor by retarding uterine contractions and cause fetal anoxia. Has produced teratogenic effects in animals at 25 times the clinical dose and some mutagenic effect in bioassays. Nasal changes were produced by epinephrine hydrochloride in long-term inhalation studies in rats and mice at concentrations of 1.5 mg/m³ or more.

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11. TOXICOLOGICAL INFORMATION, continued

CARCINOGENICITY INFORMATION: N/D. Epinephrine hydrochloride produced nasal inflammation, degeneration of epithelium and hyperplasia in carcinogenicity bioassays in mice or rats at airborne concentrations of 1.5 mg/m³ or more.

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: Dispose of in accordance with local, state and federal regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
PROPER SHIPPING NAME: N/D
HAZARD CLASS: N/D
UN NUMBER: N/D
PACKING GROUP: N/D
REPORTABLE QUANTITY: N/D
IATA/ICAO STATUS: Not Regulated

PROPER SHIPPING NAME: N/D
HAZARD CLASS: N/D
UN NUMBER: N/D
PACKING GROUP: N/D
REPORTABLE QUANTITY: N/D
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14. TRANSPORTATION INFORMATION, continued

IMO STATUS: Not Regulated
PROPER SHIPPING NAME: N/D
HAZARD CLASS: N/D
UN NUMBER: N/D
PACKING GROUP: N/D
REPORTABLE QUANTITY: N/D
FLASH POINT: Non-flammable
15. REGULATORY INFORMATION

TSCA STATUS: N/A
CERCLA STATUS: N/A
SARA STATUS: N/A
RCRA STATUS: N/A
PROP 65 (CA): N/A
16. OTHER INFORMATION

LEGEND: N/A = Not Applicable
N/D = Not Determined
N/L = Not Listed
L = Listed
C = Ceiling
S = Short-term

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16. OTHER INFORMATION, continued

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