

Buprenorphine Hydrochloride Injection

ISSUED 08/18/98

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION
-----MATERIAL NAME: Buprenorphine Hydrochloride Injection
List Number: 2012MANUFACTURER: Hospital Products Division
Abbott Laboratories
Abbott Park, Illinois 60064EMERGENCY TELEPHONE NUMBER: 1-847-937-7970
CHEMTREC TELEPHONE NUMBER: 1-800-424-93002. COMPOSITION/INFORMATION ON INGREDIENTS
-----INGREDIENT NAME: Buprenorphine Hydrochloride *
CAS/RTECS NUMBERS: 53152-21-9 / KM7758000
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: N/A
LIMITS STEL: N/A
CEILING: N/A

* Hazardous per OSHA criteria

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: In clinical use, this material is used as a narcotic analgesic to treat pain. The active ingredient is a potent drug, is toxic by ingestion, can cause psychological dependence and can harm the developing fetus. Target organs include the nervous system, respiratory system, eyes, gastrointestinal tract, cardiovascular system and fetus.

ROUTE(S) OF ENTRY: Skin: Unlikely
Inhalation: Unlikely

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3. HAZARDS INFORMATION, continued

Ingestion: Unlikely

INGESTION RATING: Possibly toxic

SKIN ABSORPTION RATING: N/D

INHALATION RATING: N/D

CORROSIVENESS RATING: N/D

SKIN CONTACT RATING: N/D

SKIN SENSITIZATION RATING: N/D

EYE CONTACT RATING: N/D

TARGET ORGANS: Nervous system, eyes, respiratory system,
gastrointestinal tract, cardiovascular system, fetus.

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

ACGIH: N/L
None

SIGNS AND SYMPTOMS: N/D. In clinical use, side effects include sedation, nausea, dizziness/vertigo, sweating, headache, hypotension, vomiting, hypoventilation, miosis, confusion, blurred vision, euphoria, weakness, fatigue, dry mouth, nervousness, depression, slurred speech, paresthesia, altered heart rate, constipation, dyspnea, cyanosis, pruritis, diplopia and visual abnormalities. Overdosage may result in respiratory depression.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. Data suggest respiratory ailments, asthma, head injury, liver dysfunction and renal dysfunction. Pre-existing central nervous system, ocular and gastrointestinal ailments. Hypothyroidism. Adrenocortical insufficiency. Concurrent use of central nervous system depressants.

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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, monitoring cardiovascular and respiratory function, as necessary. Doxapram may act as a respiratory stimulant.

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, monitoring cardiovascular and respiratory function, as necessary. Doxapram may act as a respiratory stimulant.

INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular and respiratory function, as necessary. Doxapram may act as a respiratory stimulant.

INHALATION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular and respiratory function, as necessary. Doxapram may act as respiratory stimulant.

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/A

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

FIRE FIGHTING INSTRUCTIONS: Fire fighters should wear protective clothing and self-contained breathing apparatus.

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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 prolonged exposure to light.

STORAGE: Store at controlled room temperature of 15-30 deg. C (59-86 deg. F).

SPECIAL PRECAUTIONS: Protect from prolonged exposure to light. Retain in carton until time of use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: No special provisions required.

RESPIRATORY PROTECTION: Not needed during normal product use.

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

EYE PROTECTION: Recommended if eye contact is likely.

OTHER PROTECTION: N/D

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Clear, colorless to slightly yellow liquid.

ODOR: N/D

BOILING POINT: N/D

MELTING/FREEZING POINT: N/D

VAPOR PRESSURE (mm Hg): N/D

VAPOR DENSITY (Air=1): N/D

EVAPORATION RATE: N/D

BULK DENSITY: N/D

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9. PHYSICAL AND CHEMICAL PROPERTIES, continued

SPECIFIC GRAVITY: N/D

SOLUBILITY: Soluble in water and Dextrose solutions

pH: 3.5 - 5.5

VISCOSITY: N/D

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.

INCOMPATIBILITIES: N/D

HAZARDOUS DECOMPOSITION PRODUCTS: It heated to decomposition, it emits toxic fumes.

HAZARDOUS POLYMERIZATION: N/D

11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD50 = 260 > 1000 mg/kg in rats and mice for buprenorphine hydrochloride (Toxic).

DERMAL TOXICITY: N/D

INHALATION TOXICITY: N/D

CORROSIVENESS: N/D

DERMAL IRRITATION: N/D

OCULAR IRRITATION: N/D

DERMAL SENSITIZATION: N/D

SPECIAL TARGET ORGAN EFFECTS: N/D. Buprenorphine hydrochloride is a narcotic analgesic that is used to relieve pain. It can effect the nervous system, respiration, the eyes, gastrointestinal tract and cardiovascular system. It can produce psychological dependence. In reproduction studies in animals, parenteral dosages of 0.05 mg/kg/day or more produced post-implantation loss, early fetal

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11. TOXICOLOGICAL INFORMATION, continued

deaths and extra rib formation.

CARCINOGENICITY INFORMATION: N/D. No evidence of carcinogenicity found in a 27-month study in rats receiving oral dosages of buprenorphine hydrochloride up to 57 mg/kg/day.

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/ICA0 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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