1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufactured for	Somerset Therapeutics LLC
Address	Somerset, NJ 08873
Customer care	1-800-417-9175
Product Name	Buprenorphine Hydrochloride Injection
Synonyms	17-(cyclopropylmethyl)-α-(1, 1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-α-methyl-6,14-ethenomorphinan-7-methanol, hydrochloride [5α, 7α(S)].

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Buprenorphine Hydrochloride Injection is a solution containing buprenorphine hydrochloride, an opioid analgesic used for the relief of moderate to severe pain and as an adjunct to anesthesia. In the workplace, this material should be considered potentially irritating to skin, eyes, and respiratory and a potent drug with some potential for dermal absorption. In the U.S., this product is a Schedule III controlled Substance. Based on clinical use, potential target organs include the nervous system, cardiovascular system, respiratory system, gastrointestinal system, and eyes.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA

Precautionary Statement(s)

Prevention	Do not breathe vapor or spray. Wash hands thoroughly after handling.
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Buprenorphine Hydrochloride
Chemical Formula $C_{29}H_{41}NO_4$•HCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Buprenorphine Hydrochloride	<0.033	53152-21-9	KM7758000

Non-hazardous ingredients include Water for Injection, USP and Dextrose USP monohydrate (D-Glucose monohydrate) equivalent to Dextrose USP anhydrous (5%). Hydrochloride acid, NF is added to adjust the pH.

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. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. The respiratory and cardiac status of the patients should be monitored carefully. Primary attention should be given to the re-establishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Doxapram, a respiratory stimulant, may be used. Naloxone may not be effective in reversing the respiratory depression produced by buprenorphine. Therefore, as with other potent opioids, the primary management of overdose should be the re-establishment of adequate ventilation with mechanical assistance of respiration, if required.

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use. In the U.S., this product is a Schedule III controlled Substance. Additional training and procedures may be required for proper handling of this product.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Somerset EEL**
Buprenorphine Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

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: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Buprenorphine Hydrochloride Injection is a clear, colorless solution, essentially free from visible extraneous matter.
Odor	NA
Odor Threshold	NA
pH	3.5 to 5.5
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) nitrogen oxides (NOx) and hydrogen chloride (HCl).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Buprenorphine Hydrochloride	100	LD50	Oral	>1000 800	mg/kg mg/kg	Rat Mouse
Buprenorphine Hydrochloride	100	LD50	Intravenous	62 72	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Published reports suggest that buprenorphine hydrochloride may have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

11. TOXICOLOGICAL INFORMATION: continued

Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, adverse effects include hypotension, hypertension, tachycardia, bradycardia, respiratory depression, nausea, vomiting, drowsiness, sleeping, dizziness, sweating, headache, confusion, lightheadedness, blurred vision, euphoria, dry mouth, depression, and hallucinations. After transdermal buprenorphine, local adverse effects such as pruritus, dermatitis, and erythema have been reported.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, cases of acute and chronic hypersensitivity to buprenorphine have also been reported; the most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have occurred infrequently.
Reproductive Effects	None anticipated from normal handling of this product. In reproduction studies with buprenorphine in rats, no evidence of impaired fertility at daily oral dosages up to 80 mg/kg were noted. Buprenorphine was not teratogenic in rats or rabbits after intramuscular or subcutaneous dosages up to 5 mg/kg/day, intravenous dosages up to 0.8 mg/kg/day, or after oral dosages up to 160 mg/kg/day in rats. Increases in skeletal abnormalities (e.g. extra thoracic vertebra or thoraco-lumbar ribs) were noted in rats after subcutaneous administration of 1 mg/kg/day and up and in rabbits after intramuscular administration of 5 mg/kg/day, but these increases were not statistically significant. Increases in skeletal abnormalities after oral administration were not observed in rats, and increases in rabbits (1-25 mg/kg/day) were not statistically significant. However, fetal dependence has occurred following withdrawal in women using opiates during pregnancy. FDA Pregnancy Category C.
Mutagenicity	The genotoxic potential of buprenorphine was studied in a series of assays. Results were negative in Chinese hamster bone marrow and spermatogonia cells, and negative in mouse lymphoma L5178Y assay. Results were equivocal in the Ames test: negative in studies in two laboratories, but positive in frame shift mutation at high dose (5 mg/plate) in a third study.
Carcinogenicity	Carcinogenicity studies were conducted in Sprague-Dawley rats and CD-1 mice. Buprenorphine was administered in the diet at dosages of 0.6, 5.5 and 56 mg/kg/day for 27 months in rats. Statistically significant dose-related increases in testicular interstitial (Leydig's) cell tumors occurred, according to the trend test adjusted for survival. Pairwise comparison of the high dose against control failed to show statistical significance. In the mouse study, buprenorphine was administered in the diet at dosages of 8, 50, and 100 mg/kg/day for 86 weeks. Buprenorphine was not carcinogenic in mice.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, potential target organs include the nervous system, cardiovascular system, respiratory system, gastrointestinal system, and eyes.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/ Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention
Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response
Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA
Risk Phrases NA
Safety Phrases
S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

Prepared By: Somerset Therapeutics Private Limited
Date Prepared: 31-01-2025
Date Revised: Not applicable

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