

Section 1: Identification

Common Name/Trade Name	BUPRENORPHINE HCL USP	
Supplier Information	Letco Medical 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	[5a,7a(S)]-17-(Cyclopropylmethyl)-a-(1,1-dimethylethyl)4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-a-methyl-6,14-ethenomorphinan-7-me	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4), Reproductive toxicity (Category 2)	
Signal Word	Warning	
Hazard Statement(s)	H302 Harmful if swallowed H361 Suspected of damaging fertility or the unborn child	
Pictogram(s)		
Precautionary Statement(s)	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P281 Use personal protective equipment as required. P301+P312 IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. P308+P313 IF exposed or concerned Get medical advice/attention. P330 Rinse mouth. P405 Store locked up. P501 Dispose of contents/container to an approved waste disposal plant.	
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	[5a,7a(S)]-17-(Cyclopropylmethyl)-a-(1,1-dimethylethyl)4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-a-methyl-6,14-ethenomorphinan-7-me
Common Name	Buprenorphine hydrochloride
CAS Number	53152-21-9
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If Inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In Case of Skin Contact	Wash off with soap and plenty of water. Consult a physician.
In Case of Eye Contact	Flush eyes with water as a precaution
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most Important Symptoms and Effects	The most important known symptoms and effects are described in the labeling (see section 2.2) and/or section 11

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special Hazards Arising From the Substance/Mixture	Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas
Special PPE and/or Precautions for Firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
Methods and Materials Used for Containment	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
Cleanup Procedures	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Prevent further leakage or spillage if safe to do so. Do not let product enter drain.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Conditions for Safe Storage	Keep container tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Contains no substances with occupational exposure limit values.
Appropriate Engineering Controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
PPE - Eye/Face Protection	Safety glasses with side shields conforming to EN 166 Use equipment for eye protection tested and approved under government standards such as NIOSH (US) or EN 166 (EU).
PPE - Skin Protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
PPE - Body Protection	Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
PPE - Respiratory Protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	Form: Solid Color: No data available
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	No data available
Solubility	No data available
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical Stability	Stable under recommended storage conditions.
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	No data available
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Other decomposition products-No data available

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral - rat - > 1,000 mg/kg Remarks: Behavioral: Convulsions or effect on seizure threshold. Behavioral: Change in motor activity (specific assay). Skin and Appendages: Other: Hair.
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Carcinogenicity ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Carcinogenicity NTP	No component of this product present at levels greater then or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
Carcinogenicity OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
Reproductive Toxicity	Possible risk of congenital malformation in the fetus. Suspected human reproductive toxicant. Reproductive toxicity-rat-Intramuscular. Maternal Effects: Parturition. Reproductive toxicity - rat - Intramuscular Effects on Newborn: Viability index (e.g., # alive at day 4 per # born alive). Effects on Newborn: Behavioral. Effects on Newborn: Physical Overexposure may cause reproductive disorder(s) based on tests with laboratory animals Developmental Toxicity - rat - Intramuscular Specific Developmental Abnormalities: Musculoskeletal system. Effects on Newborn: Growth statistics (e.g., reduced weight gain)
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Targer Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with and afterburner and scrubber.
Waste Treatment Methods Packaging	Dispose of unused product.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. SARA 311/312 Hazards: Acute Health Hazard, Chronic Health Hazard. Massachusetts Right To Know Components: No components are subject to the Massachusetts Right To Know Act. Pennsylvania Right To Know Components: [5a,7a(S)]-a-tert-Butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-a-methyl-6,14-ethenomorphinan-7-methanol. CAS No. 53152-21-9. New Jersey Right To Know Components: [5a,7a(S)]-a-tert-Butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-a-methyl-6,14-ethenomorphinan-7-methanol. CAS No. 53152-21-9. California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Section 16: Other Information

Prepared By	Lisa Russell
Revision Date	05/20/2015 15:49

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