

Section 1: Identification			
<b>Common Name/Trade Name</b>	BUPRENORPHINE HCL USP		
<b>Supplier Information</b>	<table border="1"> <tr> <td>Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693</td> <td><b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours)</td> </tr> </table>	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	<b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours)
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<b>Product Synonym(s)</b>	6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-(alpha)-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-(alpha)-methyl-, hydrochloride, ((alpha)S,5(alpha),7(alpha))-(9Cl)		
<b>Relevant Use(s) of Product</b>	Manufacture or Compounding of Substances		

Section 2: Hazards Identification																			
<b>Classification of Substance or Mixture</b>	Acute toxicity, oral Category 3 Acute toxicity, dermal Category 3 Acute toxicity, inhalation Category 3 Sensitization, skin Category 1 Specific target organ toxicity, single exposure Category 3 narcotic effects																		
<b>Signal Word</b>	Danger																		
<b>Hazard Statement(s)</b>	<table border="1"> <tr> <td>H301</td> <td>Toxic if swallowed</td> </tr> <tr> <td>H311</td> <td>Toxic in contact with skin</td> </tr> <tr> <td>H315</td> <td>Causes skin irritation</td> </tr> <tr> <td>H331</td> <td>Toxic if inhaled</td> </tr> </table>	H301	Toxic if swallowed	H311	Toxic in contact with skin	H315	Causes skin irritation	H331	Toxic if inhaled										
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<b>Pictogram(s)</b>																			
<b>Precautionary Statement(s)</b>	<table border="1"> <tr> <td>P221+P210</td> <td>Take any precaution to avoid mixing with combustibles. Keep away from heat/sparks/open flames/hot surfaces – No smoking.</td> </tr> <tr> <td>P233</td> <td>Keep container tightly closed.</td> </tr> <tr> <td>P240</td> <td>Ground/bond container and receiving equipment.</td> </tr> <tr> <td>P261</td> <td>Avoid breathing dust/fume/gas/mist/vapours/spray.</td> </tr> <tr> <td>P264</td> <td>Wash hands thoroughly after handling.</td> </tr> <tr> <td>P270</td> <td>Do not eat, drink or smoke when using this product.</td> </tr> <tr> <td>P272</td> <td>Contaminated work clothing should not be allowed out of the workplace.</td> </tr> <tr> <td>P280</td> <td>Wear protective gloves/protective clothing/eye protection/face protection.</td> </tr> <tr> <td>P285</td> <td>In case of inadequate ventilation wear respiratory protection.</td> </tr> </table>	P221+P210	Take any precaution to avoid mixing with combustibles. Keep away from heat/sparks/open flames/hot surfaces – No smoking.	P233	Keep container tightly closed.	P240	Ground/bond container and receiving equipment.	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.	P264	Wash hands thoroughly after handling.	P270	Do not eat, drink or smoke when using this product.	P272	Contaminated work clothing should not be allowed out of the workplace.	P280	Wear protective gloves/protective clothing/eye protection/face protection.	P285	In case of inadequate ventilation wear respiratory protection.
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<b>Hazards Not Otherwise Classified</b>	No data available																		
<b>Ingredient(s) with Unknown Toxicity</b>	No data available																		

Section 3: Composition/Information on Ingredients	
<b>Chemical Name</b>	6, 14- Ethenomorphinan- 7- methanol, 17-cyclopropylmethyl) - (alpha) - (1, 1-dimethylethyl) - 4, 5- epoxy- 18, 19-dihydro- 3-hydroxy- 6- methoxy- (alpha) - methyl- ,hydrochloride, ( (alpha) S, 5 (alpha) , 7 (alpha) ) -(9Cl
<b>Common Name</b>	Buprenorphine hydrochloride
<b>CAS Number</b>	53152-21-9
<b>Impurities and/or Stabilizing Additives</b>	No data available

## Section 4: First Aid Measures

<b>General Advice</b>	Take off immediately all contaminated clothing. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.
<b>If Inhaled</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
<b>In Case of Skin Contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. Get medical advice/attention if you feel unwell. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash clothing separately before reuse.
<b>In Case of Eye Contact</b>	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Call a physician or poison control center immediately. Continue rinsing.
<b>If Swallowed</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Ingestion
<b>Most Important Symptoms and Effects</b>	Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic skin reaction. Dermatitis. Rash.

## Section 5: Fire Fighting Measures

<b>Suitable Extinguishing Media</b>	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Suitable extinguishing media
<b>Special Hazards Arising From the Substance/Mixture</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed such as: Carbon Monoxide. Carbon dioxide. Nitrogen Oxides (NO <sub>x</sub> ). Hydrogen Chloride (HCl).
<b>Special PPE and/or Precautions for Firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask.

## Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Immediately evacuate personnel to safe areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). For personal protection, see section 8 of the SDS.
<b>Methods and Materials Used for Containment</b>	Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented.
<b>Cleanup Procedures</b>	Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

## Section 7: Handling and Storage

<b>Precautions for Safe Handling</b>	DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not use in areas without adequate ventilation. Minimize dust generation and accumulation. Avoid significant deposits of material, specially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Do not breathe dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Do not get this material in contact with eyes. Do not get this material in contact with skin. Do not get this material on clothing. Do not ingest. Use personal protective equipment as required. Wash thoroughly after handling. Wash contaminated clothing before reuse. Observe good industrial hygiene practices.
<b>Conditions for Safe Storage</b>	For storage condition, see finished product label. Protect from light. Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. Store in accordance with local/regional/national/international regulation. Store away from incompatible materials (see Section 10 of the SDS).

## Section 8: Exposure Controls/Personal Protection

<b>Components with Workplace Control Parameters</b>	No exposure standards allocated.
<b>Appropriate Engineering Controls</b>	To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powder weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. See Section 7 for additional information on proper handling and venting requirements for potent compounds. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.
<b>PPE - Eye/Face Protection</b>	Chemical goggles are recommended. Provide eyewash station and safety shower.
<b>PPE - Skin Protection</b>	Wear appropriate chemical resistant gloves. Impervious nitrile, rubber or latex gloves are recommended.
<b>PPE - Body Protection</b>	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.
<b>PPE - Respiratory Protection</b>	An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use. See Section 7 for additional information on proper handling and respirator recommendations for potent compounds.

## Section 9: Physical and Chemical Properties

<b>Appearance</b>	Appearance: Crystalline. Powder. Physical state: Solid. Form: Powder. Color: White.
<b>Upper/Lower Flammability or Explosive Limits</b>	No data available
<b>Odor</b>	Odorless.
<b>Vapor Pressure</b>	No data available
<b>Odor Threshold</b>	No data available
<b>Vapor Density</b>	No data available
<b>pH</b>	4 - 6 (1% aqueous solution)
<b>Relative Density</b>	No data available
<b>Melting Point/Freezing Point</b>	500 °F (260 °C)
<b>Solubility</b>	Solubility: (water) Slight Solubility: (other) Soluble in alcohol
<b>Initial Boiling Point and Boiling Range</b>	No data available
<b>Flash Point</b>	No data available
<b>Evaporation Rate</b>	No data available
<b>Flammability (Solid, Gas)</b>	No data available
<b>Partition Coefficient</b>	No data available
<b>Auto-Ignition Temperature</b>	No data available
<b>Decomposition Temperature</b>	No data available
<b>Viscosity</b>	No data available

## Section 10: Stability and Reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability</b>	Material is stable under normal conditions.
<b>Possibility of Hazardous Reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to Avoid</b>	Contact with incompatible materials. Avoid conditions which create dust. Moisture. Sunlight. Heat, flames and sparks.
<b>Incompatible Materials</b>	None known.
<b>Hazardous Decomposition Products</b>	May decompose upon heating to produce corrosive and/or toxic fumes.

## Section 11: Toxicological Information

<b>Acute Toxicity - LD50 Oral</b>	Oral Acute LD50 Mouse 260 mg/kg
<b>Acute Toxicity - Inhalation</b>	Toxic if inhaled. Prolonged inhalation may be harmful. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing.
<b>Acute Toxicity - Dermal</b>	Toxic in contact with skin. Dust or powder may irritate the skin. May produce narcotic effects if absorbed through skin. Symptoms may parallel ingestion. May cause sensitization by skin contact
<b>Acute Toxicity - Eye</b>	Dust or powder may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body.
<b>Skin Corrosion/Irritation</b>	No data available
<b>Serious Eye Damage/Irritation</b>	No data available
<b>Respiratory or Skin Sensitization</b>	No data available
<b>Germ Cell Mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity IARC</b>	No data available
<b>Carcinogenicity ACGIH</b>	No data available
<b>Carcinogenicity NTP</b>	No data available
<b>Carcinogenicity OSHA</b>	No data available
<b>Reproductive Toxicity</b>	No data available
<b>Specific Target Organ Toxicity - Single Exposure</b>	No data available
<b>Specific Target Organ Toxicity - Repeated Exposure</b>	No data available
<b>Aspiration Hazard</b>	No data available

## Section 12: Ecological Information

<b>Toxicity</b>	No data available
<b>Persistence and Degradability</b>	No data available
<b>Bio-accumulative Potential</b>	No data available
<b>Mobility in Soil</b>	No data available
<b>Other Adverse Effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## Section 13: Disposal Considerations

<b>Waste Treatment Methods Product</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Notify site Controlled Substance Compliance officer and local DEA office or competent authority for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). Dispose of contents/container (in accordance with related regulations).
<b>Waste Treatment Methods Packaging</b>	Dispose in accordance with all applicable regulations.
<b>Special Precautions Landfill or Incinerations</b>	No data available
<b>Other Information</b>	No data available

## Section 14: Transport Information

<b>UN Number</b>	UN3288
<b>UN Proper Shipping Name</b>	Toxic solid, inorganic, n.o.s. (BUPRENORPHINE HYDROCHLORIDE)
<b>Transport Hazard Class(es)</b>	6.1(PGIII)
<b>Packaging Group</b>	III
<b>Environmental Hazards</b>	N/A

## Section 15: Regulatory Information

Superfund Amendments and Reauthorization Act of 1986 (SARA) Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No Hazard categories SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous Yes chemical Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act Not regulated.(SDWA) Drug Enforcement Schedule III - 9064 Administration (DEA) (21 CFR 1308.11-15) US state regulations US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100) Not listed. US. Massachusetts RTK - Substance List Not regulated. US. New Jersey Worker and Community Right-to-Know Act Not listed. US. Pennsylvania Worker and Community Right-to-Know Law Not listed. US. Rhode Island RTK Not regulated.US. California Proposition 65 Not Listed. International Inventories Country(s) or region Inventory name On inventory (yes/no)\* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) No Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) No Europe European Inventory of Existing Commercial Chemical Yes Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) No Korea Existing Chemicals List (ECL) No New Zealand New Zealand Inventory Yes Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No \*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing Country(s)

## Section 16: Other Information

<b>Additional Information</b>	
<b>Prepared By</b>	Lisa Russell
<b>Revision Date</b>	05/13/2019 16:41

### Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.