

Section 1: Identification			
Common Name/Trade Name	NALBUPHINE HCL		
Supplier Information	<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>IN CASE OF EMERGENCY: 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	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
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Product Synonym(s)	opioid agonist/antagonist analgesic* (5.alpha.,6.alpha.)-17-(Cyclobutylmethyl)-4,5-epoxymorphinan-3,6,14-triol hydrochloride * Nalbuphine Hydrochloride Analytical Research Standard-(FOR R&D USE ONLY)		
Relevant Use(s) of Product	Manufacture or Compounding of Substances		

Section 2: Hazards Identification																					
Classification of Substance or Mixture	Acute toxicity, Oral (Category 4), Acute toxicity, Inhalation (Category 4), Specific target organ toxicity, single exposure (Category 3) narcotic effects																				
Signal Word	Warning																				
Hazard Statement(s)	<table border="1"> <tr> <td>H302</td> <td>Harmful if swallowed</td> </tr> <tr> <td>H332</td> <td>Harmful if inhaled</td> </tr> <tr> <td>H336</td> <td>May cause drowsiness or dizziness</td> </tr> </table>	H302	Harmful if swallowed	H332	Harmful if inhaled	H336	May cause drowsiness or dizziness														
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Pictogram(s)																					
Precautionary Statement(s)	<table border="1"> <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>P271</td> <td>Use only outdoors or in a well-ventilated area.</td> </tr> <tr> <td>P301+P312</td> <td>IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell.</td> </tr> <tr> <td>P304+P340</td> <td>IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing.</td> </tr> <tr> <td>P312</td> <td>Call a POISON CENTER or doctor/physician if you feel unwell.</td> </tr> <tr> <td>P330</td> <td>Rinse mouth.</td> </tr> <tr> <td>P405</td> <td>Store locked up.</td> </tr> <tr> <td>P501</td> <td>Dispose of contents/container to an approved waste disposal plant.</td> </tr> </table>	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.	P271	Use only outdoors or in a well-ventilated area.	P301+P312	IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell.	P304+P340	IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing.	P312	Call a POISON CENTER or doctor/physician if you feel unwell.	P330	Rinse mouth.	P405	Store locked up.	P501	Dispose of contents/container to an approved waste disposal plant.
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Hazards Not Otherwise Classified	None known.																				
Ingredient(s) with Unknown Toxicity	No data available																				

Section 3: Composition/Information on Ingredients	
Chemical Name	Nalbuphine Hydrochloride
Common Name	Nalbuphine Hydrochloride
CAS Number	23277-43-2
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures	
General Advice	Call a POISON CENTER or doctor/physician if you feel unwell. Ensure that medical personell are aware of the material(s) involved, and take precautions to protect themselves.
If Inhaled	If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Call a POISON CENTER or doctor/physician if you feel unwell.
In Case of Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If Swallowed	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. 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. Rinse mouth thoroughly. If vomiting occurs, keep head low so that stomach content doesn't get into lungs.
Most Important Symptoms and Effects	Not Available

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water. Dry chemical powder. Alcohol foam. Carbon dioxide (CO ₂).
Special Hazards Arising From the Substance/Mixture	Not applicable.
Special PPE and/or Precautions for Firefighters	In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Ensure adequate ventilation. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Follow handling guidance: LABORATORY: *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices. *No local exhaust ventilation required for transfer/handling of quantities of powder less than 100g (total weight transferred or handled). However, if the source container contains 2kg or more, pilot plant practices apply. *No local exhaust ventilation required for solutions of these compounds. *Quantities of solid above 100g require use of a powders weighing hood or other approved containment/ventilation system. *High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system. *Develop cleaning procedures and techniques that limit potential exposure. PILOT PLANT PRODUCTION: *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses and safety shoes. Use good manufacturing practices (i.e., cGMPs). *Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. *Where open handling of powders occurs, use a powdered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate. *Protective garments (coveralls, Tyveks, lab coat) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. *High energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system. *Develop cleaning procedures and techniques that limit potential exposure.
Methods and Materials Used for Containment	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). 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. 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. Do not flush to sewer. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). 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. 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. Do not flush to sewer. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling	Do not use in areas without adequate ventilation. Avoid breathing dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with eyes. Do not ingest. In case of insufficient ventilation, wear suitable respiratory equipment. Wash hands thoroughly after handling. When using, do not eat, drink or smoke. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Handle and open container with care.
Conditions for Safe Storage	Store locked up. Keep container tightly closed. Store up to 25°C. Store in a well-ventilated place. Keep away from heat and sources of ignition. Use care in handling/storage. Store in accordance with local/regional/national/international regulation.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No data available
Appropriate Engineering Controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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. Ensure adequate ventilation, especially in confined areas.
PPE - Eye/Face Protection	Chemical goggles are recommended. Provide eyewash station and safety shower.
PPE - Skin Protection	Wear protective gloves.
PPE - Body Protection	Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.
PPE - Respiratory Protection	Where open handling of powder occurs, use a powdered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.

Section 9: Physical and Chemical Properties

Appearance	Powder. White.
Upper/Lower Flammability or Explosive Limits	Not available
Odor	Odorless
Vapor Pressure	Not available.
Odor Threshold	Not available
Vapor Density	Not available.
pH	Not available
Relative Density	Not available
Melting Point/Freezing Point	440.6-449.6 Å°F (227-232Å°C)
Solubility	Water Soluble
Initial Boiling Point and Boiling Range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not available
Partition Coefficient	Not available
Auto-Ignition Temperature	Not available
Decomposition Temperature	Not available
Viscosity	Not available

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	Not available
Conditions to Avoid	Not available.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides (NOx). Halogens.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Not available
Acute Toxicity - Inhalation	Harmful if inhaled. Inhalation of dusts may cause respiratory irritation.
Acute Toxicity - Dermal	Health injuries are not known or expected under normal use.
Acute Toxicity - Eye	Dust or powder may irritate eye tissue.
Skin Corrosion/Irritation	Due to lack of data the classification is not possible.
Serious Eye Damage/Irritation	Due to lack of data the classification is not possible.
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity	Due to the lack of data the classification is not possible.
Carcinogenicity IARC	This product is not considered to be a carcinogen by IARC.
Carcinogenicity ACGIH	This product is not considered to be a carcinogen by ACGIH
Carcinogenicity NTP	This product is not considered to be a carcinogen by NTP.
Carcinogenicity OSHA	This product is not considered to be a carcinogen by OSHA.
Reproductive Toxicity	Due to lack of data the classification is not possible.
Specific Target Organ Toxicity - Single Exposure	Narcotic effects.
Specific Target Organ Toxicity - Repeated Exposure	Due to lack of data the classification is not possible.
Aspiration Hazard	Due to lack of data the classification is not possible.

Section 12: Ecological Information

Toxicity	This product has no known eco-toxicological effects.
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	Not established.
Mobility in Soil	Not available.
Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13: Disposal Considerations

Waste Treatment Methods Product	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b) (4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Waste Treatment Methods Packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
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

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. CERCLA/SARA Hazardous Substances - Not applicable. TSCA exempt status. TSCA Section 12(b) Export Notification (40CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not listed. CERCLA (Superfund) reportable quantity None. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories: Immediate Hazard - Yes, Delayed Hazard-No, Fire Hazard - No, Pressure Hazard - No, Reactivity Hazard - No. SARA 302 Extremely hazardous substance: Not listed. SARA 311/312 Hazardous chemical: Yes. 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 (SDWA): Not regulated. US state regulations: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. 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: Australia: Australian Inventory of Chemical Substances (AICS), On inventory (yes/no)*: No. Canada Domestic Substances List (DSL), On inventory (yes/no)*: No. Canada Non-Domestic Substances List (NDSL), On inventory (yes/no)*: No. China Inventory of Existing Chemical Substances in China (IECSC), On inventory (yes/no)*: No. Europe European Inventory of Existing Commercial Chemical Substances (EINECS), On inventory (yes/no)*: Yes. Europe European List of Notified Chemical Substances (ELINCS), On inventory (yes/no)*: No. Japan Inventory of Existing and New Chemical Substances (ENCS), On inventory (yes/no)*: No. Korea Existing Chemicals List (ECL), On inventory (yes/no)*: No. New Zealand, New Zealand Inventory, On inventory (yes/no)*: No. Philippines, Philippine Inventory of Chemicals and Chemical Substances (PICCS), On inventory (yes/no)*: No. United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory, On inventory (yes/no)*: 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

Additional Information	N/A
Prepared By	Lisa Russell
Revision Date	01/10/2019 16:55

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.