


## Section 1: Identification

<b>Common Name/Trade Name</b>	NALBUPHINE HCL	
<b>Supplier Information</b>	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)
<b>Product Synonym(s)</b>	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)	
<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 4), Acute toxicity, Inhalation (Category 4), Specific target organ toxicity, single exposure (Category 3) narcotic effects	
<b>Signal Word</b>	Warning	
<b>Hazard Statement(s)</b>	H302 H332 H336	Harmful if swallowed Harmful if inhaled May cause drowsiness or dizziness
<b>Pictogram(s)</b>		
<b>Precautionary Statement(s)</b>	P261 P264 P270 P271 P301+P312 P304+P340 P312 P330 P405 P501	Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Store locked up. Dispose of contents/container to an approved waste disposal plant.
<b>Hazards Not Otherwise Classified</b>	None known.	
<b>Ingredient(s) with Unknown Toxicity</b>	No data available	

## Section 3: Composition/Information on Ingredients

<b>Chemical Name</b>	Nalbuphine Hydrochloride
<b>Common Name</b>	Nalbuphine Hydrochloride
<b>CAS Number</b>	23277-43-2
<b>Impurities and/or Stabilizing Additives</b>	No data available

## Section 4: First Aid Measures

<b>General Advice</b>	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.
<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. Call a POISON CENTER or doctor/physician if you feel unwell.
<b>In Case of Skin Contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>In Case of Eye Contact</b>	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
<b>If Swallowed</b>	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.
<b>Most Important Symptoms and Effects</b>	Not Available

## Section 5: Fire Fighting Measures

<b>Suitable Extinguishing Media</b>	Water. Dry chemical powder. Alcohol foam. Carbon dioxide (CO <sub>2</sub> ).
<b>Special Hazards Arising From the Substance/Mixture</b>	Not applicable.
<b>Special PPE and/or Precautions for Firefighters</b>	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

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	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.
<b>Methods and Materials Used for Containment</b>	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.
<b>Cleanup Procedures</b>	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

<b>Precautions for Safe Handling</b>	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.
<b>Conditions for Safe Storage</b>	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

<b>Components with Workplace Control Parameters</b>	No data available
<b>Appropriate Engineering Controls</b>	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.
<b>PPE - Eye/Face Protection</b>	Chemical goggles are recommended. Provide eyewash station and safety shower.
<b>PPE - Skin Protection</b>	Wear protective gloves.
<b>PPE - Body Protection</b>	Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.
<b>PPE - Respiratory Protection</b>	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

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

## Section 10: Stability and Reactivity

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

## Section 11: Toxicological Information

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

## Section 12: Ecological Information

<b>Toxicity</b>	This product has no known eco-toxicological effects.
<b>Persistence and Degradability</b>	No data is available on the degradability of this product.
<b>Bio-accumulative Potential</b>	Not established.
<b>Mobility in Soil</b>	Not 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>	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.
<b>Waste Treatment Methods Packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<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>	Not dangerous goods.
<b>UN Proper Shipping Name</b>	N/A
<b>Transport Hazard Class(es)</b>	N/A
<b>Packaging Group</b>	N/A
<b>Environmental Hazards</b>	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

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

### Disclaimer

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