


Section 1: Identification

Common Name/Trade Name	NALTREXONE HCL (ANHYDROUS)	
Supplier Information	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)
Product Synonym(s)	17-9cyclopropylmethyl)-4, 5alpha-epoxy-3,14-dihydroxy-morphinian-6-one-hydrochloride; naltrexone hcl milled; naltrexone hydrochloride cru; naltrexone hydrochloride	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P264 P301+P312+P330 P501	Wash hands thoroughly after handling. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	Not classified	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	(5ALPHA)- 17 -(CYCLOPROPYLMETHYL)-4,5-EPOXY-3, 14-DIHYDROXYMORPHINAN-6-ONE HYDROCHLORIDE
Common Name	NALTREXONE HYDROCHLORIDE
CAS Number	16676-29-2
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	No data available.
If Inhaled	Remove to fresh air. Administer artificial respiration if breathing has ceased. IMMEDIATELY consult a physician.
In Case of Skin Contact	In case of skin contact, IMMEDIATELY flush exposed skin thoroughly with plenty of water. While wearing protective gloves, remove any contaminated clothing, including shoes and continue to wash skin thoroughly with soap and water for at least 15 minutes. Get IMMEDIATE medical attention.
In Case of Eye Contact	In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.
If Swallowed	Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.
Most Important Symptoms and Effects	The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material. Naltrexone hydrochloride is harmful by inhalation, in contact with skin, and if swallowed. It may cause sensitization by inhalation and by contact . Naltrexone hydrochloride is an opioid antagonist and is used for the treatment of opiate and alcohol dependence. Acute exposure to naltrexone hydrochloride may cause fatigue, sleepiness, decreased concentration, dizziness, lightheadedness, motor dysfunction, fainting, headache, pain, nervousness, agitation, behavioral changes, anxiety, depression, confusion, hallucinations, constriction of pupils, seizure disorders, dry mouth, gastrointestinal discomfort, nausea, loss of appetite, vomiting, abdominal pain, diarrhea, joint pain, respiratory depression, inflammation of the throat, rash, sweating, cardiac irregularities, lung edema, changes in reproductive hormones, and reproductive function changes. Chronic exposure may cause difficulty in sleeping, joint and muscle pain and muscle cramps.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable Extinguishing media: Carbon dioxide (CO ₂), extinguishing powder or water spray.
Special Hazards Arising From the Substance/Mixture	Thermal Decomposition products: Hydrogen chloride (HCl). Nitrogen oxides (NO _x). Carbon monoxide (CO). Carbon dioxide (CO ₂). Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. This material has been shown to be particularly sensitive to ignition by electrostatic discharges. All conductive plant items and operations personnel handling this material should be suitably grounded. Consideration should also be given to the possibility of ignition due to electrostatic discharges from accumulating powder and restricting the use of low-conductivity materials of construction.
Special PPE and/or Precautions for Firefighters	Wear full protective clothing and self-contained breathing apparatus (SCBA).

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in section 8. Keep personnel away from the cleanup area.
Methods and Materials Used for Containment	All spills should be handled according to site requirements and based on precautions cited in the SDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.
Cleanup Procedures	All spills should be handled according to site requirements and based on precautions cited in the SDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid dust generation. Avoid breathing dust. Avoid contact with skin and clothing. Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture. Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.
Conditions for Safe Storage	Store at 15-25 deg. C. Store in a cool, dry, well-ventilated area. Store in adequately sealed container. Avoid moisture.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Occupational Exposure Band (OEB): OEB 3: 10-100 mcg/m. Materials in an OEB 3 Category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site and industrial hygiene staff for guidance on handling and control strategies. Internal Occupational Exposure Limit (8-hr TWA): 50.0 mcg/m.
Appropriate Engineering Controls	The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of PPE may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.
PPE - Eye/Face Protection	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
PPE - Skin Protection	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
PPE - Body Protection	In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suite is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.
PPE - Respiratory Protection	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Section 9: Physical and Chemical Properties

Appearance	White to off-white crystalline solid, Crystalline powder
Upper/Lower Flammability or Explosive Limits	See Section 5 for flammability/explosivity information.
Odor	Odorless
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	274-276
Solubility	>5 g/100 ml @ 20 deg C
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	Stable under normal conditions.
Chemical Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous decomposition is expected if used according to manufacturer's specifications.
Conditions to Avoid	None known.
Incompatible Materials	None known.
Hazardous Decomposition Products	No dangerous decomposition is expected if used according to manufacturer's specifications.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Oral LD50: 1450 mg/kg (rat); Oral LD50: 1100 mg/kg (mouse)
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	Alkaloids/opioids may cause allergic reactions.
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	Alkaloids/opioids may cause allergic reactions.
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	This material or product has not been evaluated for carcinogenicity.
Carcinogenicity ACGIH	This material or product has not been evaluated for carcinogenicity.
Carcinogenicity NTP	This material or product has not been evaluated for carcinogenicity.
Carcinogenicity OSHA	This material or product has not been evaluated for carcinogenicity.
Reproductive Toxicity	Naltrexone Hydrochloride: Intraperitoneal TDLo (1-22 days post conception): 1100 mg/kg (female rat). Naltrexone hydrochloride anhydrous caused effects on newborns including decreased weight gain.
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	This material has not been tested for ecotoxicity.
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	Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).
Waste Treatment Methods Packaging	Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.
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	No data available

Section 15: Regulatory Information

TSCA Listing: This material or product is not subject to TSCA requirements.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
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