


## Section 1: Identification

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|-----------------------------------|--|---|
| <b>Common Name/Trade Name</b>     | NALTREXONE HCL (ANHYDROUS)   |   |
| <b>Supplier Information</b>       | Letco Medical, LLC<br>1316 Commerce Drive NW<br>Decatur, AL 35601<br>1 (800) 239-5288<br>+1 (734) 843-4693   | <b>IN CASE OF EMERGENCY:</b><br>Chemtrec<br>1 (800) 424-9300 (24 hours)<br>NSW Poisons Information Centre: 131 126 (24 hours) |
| <b>Distributor Name</b>           | Bella Corp Trading Pty Ltd<br>6/34 Dominions Road, Ashmore QLD 4214, Australia<br>Telephone: 07 5597 4169<br>Email: <a href="mailto:bellacorp@bellacorp.com.au">bellacorp@bellacorp.com.au</a> |   |
| <b>Product Synonym(s)</b>         | 17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride   |   |
| <b>Relevant Use(s) of Product</b> | Manufacture or Compounding of Substances   |   |

## Section 2: Hazards Identification

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| <b>Classification of Substance or Mixture</b> | Acute toxicity, oral (Category 4), Reproductive toxicity (Category 2), Specific target organ toxicity, single exposure (Category 3) narcotic effects   |  |
| <b>Signal Word</b>                            | Warning  |  |
| <b>Hazard Statement(s)</b>                    | H302 Harmful if swallowed<br>H336 May cause drowsiness or dizziness<br>H361 Suspected of damaging fertility or the unborn child  |  |
| <b>Pictogram(s)</b>                           |    |  |
| <b>Precautionary Statement(s)</b>             | P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.<br>P233 Keep container tightly closed.<br>P261 Avoid breathing dust/fume/gas/mist/vapours/spray.<br>P264 Wash hands thoroughly after handling.<br>P270 Do not eat, drink or smoke when using this product.<br>P271 Use only outdoors or in a well-ventilated area.<br>P280 Wear protective gloves/protective clothing/eye protection/face protection.<br>P301+P312 IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell.<br>P304+P340 IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing.<br>P308+P313 IF exposed or concerned Get medical advice/attention.<br>P330 Rinse mouth.<br>P403 Store in a well-ventilated place.<br>P405 Store locked up.<br>P501 Dispose of contents/container to an approved waste disposal plant. |  |
| <b>Hazards Not Otherwise Classified</b>       | Not classified   |  |
| <b>Ingredient(s) with Unknown Toxicity</b>    | No data available  |  |

## Section 3: Composition/Information on Ingredients

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| <b>Chemical Name</b>                           | 17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride |
| <b>Common Name</b>                             | NALTREXONE HYDROCHLORIDE   |
| <b>CAS Number</b>                              | 16676-29-2   |
| <b>Impurities and/or Stabilizing Additives</b> | No data available  |

## Section 4: First Aid Measures

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| <b>General Advice</b>                      | IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance                                 |
| <b>If Inhaled</b>                          | 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.  |
| <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>              | Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.  |
| <b>If Swallowed</b>                        | Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.  |
| <b>Most Important Symptoms and Effects</b> | May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes. Indication of immediate medical attention and special treatment needed: Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed |

## Section 5: Fire Fighting Measures

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| <b>Suitable Extinguishing Media</b>                       | Suitable Extinguishing media: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Unsuitable extinguishing media: Do not use water jet as an extinguisher, as this will spread the fire.   |
| <b>Special Hazards Arising From the Substance/Mixture</b> | During fire, gases hazardous to health may be formed such as: Carbon oxides. Nitrogen Oxides. Hydrogen Chloride (HCl).  |
| <b>Special PPE and/or Precautions for Firefighters</b>    | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. In case of fire and/or explosion do not breathe fumes. Use water spray to cool unopened containers. Move containers from fire area if you can do so without risk. Use standard firefighting procedures and consider the hazards of other involved materials. Follow handling guidance appropriate for OEB72 compounds, (see section 7). Specific methods General fire hazards Material will burn in a fire. |

## Section 6: Accidental Release Measures

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| <b>Personal Precautions, Protective Equipment and Emergency Procedures</b> | Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. Follow handling guidance appropriate for OEB-2 compounds, (see section 7). |
| <b>Methods and Materials Used for Containment</b>                          | Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. This product is miscible in water. Stop the flow of material, if this is without risk. Avoid discharge into drains, water courses or onto the ground.   |
| <b>Cleanup Procedures</b>  | Large Spills: Wet down with water and dike for later disposal. Absorb in vermiculite, dry sand or earth and place into containers. Shovel the material into waste container. Following product recovery, flush area with water. Retain and dispose of contaminated wash water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  |

## Section 7: Handling and Storage

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| <b>Precautions for Safe Handling</b> | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Do not taste or swallow. Avoid breathing dust. Avoid prolonged exposure. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. NALTREXONE HYDROCHLORIDE has pharmacological activity and is classified as an OEB72* material. Handling practices for OEB-2 substances are described below. 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 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply. *No local exhaust ventilation required for solutions of these compounds. *Quantities of solid above 100 g 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. |
| <b>Conditions for Safe Storage</b>   | For storage condition, see finished product label. Store locked up. Store in tightly closed container. Store in a cool place. Store in a well-ventilated place. Store away from heat and light. Store away from incompatible materials (see Section 10 of the SDS).  |

## Section 8: Exposure Controls/Personal Protection

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| <b>Components with Workplace Control Parameters</b> | The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits. OEG - 50 ug/m <sup>3</sup> 8-hour time-weighted average. STEG - 500 ug/m <sup>3</sup> 15-minute average. Biological limit values: No biological exposure limits noted for the ingredient(s). NALTREXONE HYDROCHLORIDE falls within Occupational Exposure Band 2B (OEB 2B) covering the 87-hour time-weighted average range >10 - 100 ug/m <sup>3</sup> . Short7term Exposure Guideline (STEG), if listed, is the value for a 15-minute exposure time.  |
| <b>Appropriate Engineering Controls</b>             | Good general ventilation 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 engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. 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. Eye wash fountain and emergency showers are recommended. Observe any medical surveillance requirements. Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. See Section 7 for additional information on occupational control measures appropriate for OEB-2 compounds. |
| <b>PPE - Eye/Face Protection</b>                    | Chemical goggles are recommended  |
| <b>PPE - Skin Protection</b>                        | Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.  |
| <b>PPE - Body Protection</b>                        | Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Wear appropriate thermal protective clothing, when necessary.  |
| <b>PPE - Respiratory Protection</b>                 | Where open handling of powders occurs, use a powered, 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

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| <b>Appearance</b>                                   | Physical state: Solid. Form: Powder. Color: Off-white or 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>                             | 1.3   |
| <b>Melting Point/Freezing Point</b>                 | Not available.  |
| <b>Solubility</b>                                   | Soluble in water.   |
| <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>                    | Decomposition to 270°C.   |
| <b>Viscosity</b>                                    | Not available.  |

## Section 10: Stability and Reactivity

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| <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> | No dangerous reaction known under conditions of normal use.                                   |
| <b>Conditions to Avoid</b>                | Contact with incompatible materials.  |
| <b>Incompatible Materials</b>             | Strong oxidizing agents.  |
| <b>Hazardous Decomposition Products</b>   | No hazardous decomposition products are known.  |

## Section 11: Toxicological Information

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| <b>Acute Toxicity - LD50 Oral</b>                         | Harmful if swallowed. Oral Acute LD50 Mouse 1100 mg/kg Rat 1450 mg/kg  |
| <b>Acute Toxicity - Inhalation</b>                        | May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dust may irritate respiratory system. Prolonged inhalation may be harmful. |
| <b>Acute Toxicity - Dermal</b>                            | Dust or powder may irritate the skin.  |
| <b>Acute Toxicity - Eye</b>                               | Dust may irritate the eyes.  |
| <b>Skin Corrosion/Irritation</b>                          | Prolonged skin contact may cause temporary irritation.   |
| <b>Serious Eye Damage/Irritation</b>                      | Direct contact with eyes may cause temporary irritation.   |
| <b>Respiratory or Skin Sensitization</b>                  | Not a respiratory sensitizer. This product is not expected to cause skin sensitization.  |
| <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>                               | Not classifiable as to carcinogenicity to humans. Not listed.  |
| <b>Carcinogenicity ACGIH</b>                              | Not classifiable as to carcinogenicity to humans.  |
| <b>Carcinogenicity NTP</b>                                | Not classifiable as to carcinogenicity to humans.  |
| <b>Carcinogenicity OSHA</b>                               | Not classifiable as to carcinogenicity to humans. Not regulated.   |
| <b>Reproductive Toxicity</b>                              | Suspected of damaging fertility or the unborn child.   |
| <b>Specific Target Organ Toxicity - Single Exposure</b>   | May cause drowsiness and dizziness.  |
| <b>Specific Target Organ Toxicity - Repeated Exposure</b> | Not classified.  |
| <b>Aspiration Hazard</b>                                  | Not an aspiration hazard.  |

## Section 12: Ecological Information

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|--------------------------------------|---|
| <b>Toxicity</b>                      | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.          |
| <b>Persistence and Degradability</b> | No data is available on the degradability of this substance.  |
| <b>Bio-accumulative Potential</b>    | Partition coefficient n-octanol / water (log Kow) 0.534 1.84  |
| <b>Mobility in Soil</b>              | This product is water soluble and may disperse in soil.   |
| <b>Other Adverse Effects</b>         | 100% of the substance consists of component(s) of unknown acute hazards to the aquatic environment. 100% of the substance consists of component(s) of unknown long-term hazards to the aquatic environment. |

## Section 13: Disposal Considerations

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| <b>Waste Treatment Methods Product</b>               | Notify site Drug Enforcement Administration compliance officer and local DEA office 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-2 compounds, (see Section 7). Dispose of contents/container in accordance with local/regional/national/international regulations.  |
| <b>Waste Treatment Methods Packaging</b>             | Dispose in accordance with all applicable regulations. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Since emptied containers may retain product residue, follow label warnings even after container is emptied. 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

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|-----------------------------------|---------------------|
| <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>      | No data available   |

## 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. TSCA exempt status. CERCLA (Superfund) reportable quantity None CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSEA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. US federal regulations Toxic Substances Control This substance is not on the TSCA 8(b) inventory or is designated "inactive". Act (TSCA) TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. SARA 311/312 Hazardous Yes chemical Acute toxicity (any route of exposure) Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (EAPs) 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) US state regulations California Proposition 65 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. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov). International Inventories Country(s) or region Inventory name On inventory (yes/no)\* Australia Australian Inventory of Chemical Substances (AICS) No 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 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 Country(s) or region Inventory name On inventory (yes/no)\* New Zealand New Zealand Inventory No Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) Taiwan Taiwan Chemical Substance Inventory (TCSI) Yes 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

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| <b>Additional Information</b> | Further information May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage. May cause damage to the liver. Information in drug literature indicates this substance has been shown to have embryocidal effects in experimental animals at large doses. May produce acute withdrawal symptoms in individuals physically dependent on opioids. 100% of the substance consists of component(s) of unknown acute dermal toxicity. 100% of the substance consists of component(s) of unknown acute inhalation toxicity. |
| <b>Prepared By</b>            | Gabe Peluso  |
| <b>Revision Date</b>          | 06/06/2023 15:23   |

### Disclaimer

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