Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Naltrexone Hydrochloride USP Anhydrous
Commercial Name Not available
Product Use Medication: Antagonist to Narcotics
Restrictions On Use Not available

Product Code 50-4377

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute toxicity, oral Category 4 Sensitization, skin Category 1 Germ cell mutagenicity Category 2

Signal Word WARNING

Hazard Statement(s) Harmful if swallowed. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. If exposed or concerned: Get medical advice/attention.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents /container in accordance with local /regional/national/intemational regulation

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components 17- (Cyclopropylmethyl)-4,5- epoxy - 3,14 - dihydroxymorphinan-6 -one hydrochloride
% By Weight 100
CAS# 16676-29-2
Molecular Weight Not available.
Chemical Formula C20H23NO4.ClH
Synonym(s) 17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
(5a)- 17- (Cyclopropylmethyl)-4,5-epoxy - 3,14 - dihydroxymorphinan-6 -one hydrochloride	16676-29-2	100	N/A	N/A

Section 4: First-Aid Measures

Inhalation 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.

Skin Contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye Contact Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion 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.

Symptoms/Effects

Acute May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes.

Delayed May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2)

Unsuitable Extinguishing Media

Do not use water jet as an extinguisher, as this will spread the fire.

Products of Combustion

During fire, gases hazardous to health may be formed such as: Carbon oxides. Nitrogen Oxides. Hydrogen Chloride (HCl).

Firefighters Special Equipment and Precautions

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 OEB-2 compounds, (see section 7).

Section 6: Accidental Release Measures

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). 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. 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.Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

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. 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). CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Administration or competent authority regulations. NALTREXONE HYDROCHLORIDE has pharmacological activity and is classified as an OEB-2* 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. 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 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. *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.

Section 8: Exposure Controls/Personal Protection

Exposure Limits

NALTREXONE HYDROCHLORIDE (CAS 16676-29-2) OEG 50um/m3 8-hour time-weighted avergae.
NALTREXONE HYDROCHLORIDE (CAS 16676-29-2) STEG 500um/m3 15 minute avergae.

Engineering Controls

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.

Personal Protection

Eye/face protection: Chemical goggles are recommended. Skin protection: Hand protection Wear appropriate chemical resistant gloves. Nitrile or butyl rubber gloves are recommended. Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Respiratory protection: 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. Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

Section 9: Physical and Chemical Properties

Appearance	Solid Off-white or white powder
Odor	Odorless
Odor Threshold	Not available.

Melting Point	Not available	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	Not available.
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Decomposition to 270 °C.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	1.84	**Evaporation Rate**	Not available.
Flash Point	Not available.	**Autoignition temperature**	Not available.
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	Soluble in water
Other	Explosive properties Not explosive. Molecular formula C20H23NO4.ClH Molecular weight 377.86 g/mol Oxidizing properties Not oxidizing.

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions.
Hazardous Polymerization	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	No hazardous decomposition products are known.

Section 11: Toxicological Information

RTECS Not Available

Acute Toxicity
Harmful if swallowed.

Skin Corrosion/Irritation
Prolonged skin contact may cause temporary irritation.

Serious Eye Damage/Irritation
Direct contact with eyes may cause temporary irritation

Respiratory or Skin Sensitization
Due to lack of data the classification is not possible. May cause allergic skin disorders in sensitive individuals.

Germ Cell Mutagenicity
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity
Not classifiable as to carcinogenicity to humans.

Reproductive Toxicity
Suspected of damaging fertility or the unborn child.

Routes of Entry
Inhalation. Ingestion.

Symptoms Related to Exposure
May cause drowsiness and dizziness.

Potential Health Effects
Not available

Target Organ(s) Not available

Section 12: Ecological Information

Ecotoxicity
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.

Persistance and Degradability
No data is available on the degradability of this product.

Bioaccumulative Potential
Partition coefficient n-octanol / water (log Kow) 0.534 1.84

Mobility in Soil
This product is water soluble and may disperse in soil.

Other Adverse Effects
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

Waste Disposal
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 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).

Disposal of Container
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.

Other Considerations
Not available

Section 14: Transport Information

DOT Classification
DOT Not regulated as dangerous goods. IATA Not regulated as dangerous goods. IMDG Not regulated as dangerous goods. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

Section 15: Regulatory Information

Regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA exempt status. TSCA Section 12(b) Export Notification (40 CFR 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 - Yes 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 Country(s) or region Inventory name 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 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 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) 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).

Other

Not controlled under WHMIS (Canada). DSCL (EEC): R22- Harmful if swallowed. S22- Do not breathe dust. S36- Wear suitable protective clothing.

Section 16: Other Information

The information given in this document has been compiled on the basis of the best available knowledge; it does not imply that it is accurate or complete in all cases. It is the user responsibility to satisfy themselves as to the suitability of the information for his/her own particular use. Toxicological data are taken from RTECS.