

**Safety Data Sheet**

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

Section 1: Identification**Product Name** NALTREXONE HYDROCHLORIDE USP DIHYDRATE**Commercial Name** N/A**Product Use** Active Pharmaceutical Ingredient**Restrictions On Use** N/A**Product Code** 30-5086**Company** PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300**Section 2: Hazard(s) Identification****OSHA Haz Com:** Acute Toxicity, 4
CFR 1910.1200**Signal Word** WARNING**Hazard Statement(s)** Harmful if swallowed**Pictogram(s) or Symbol(s)****Precautionary Statement(s):**

Prevention	P261 Avoid breathing dust/fume/gas/mist/vapors/spray P264 Wash thoroughly after handling P270 Do not eat, drink or smoke when using this product P280 Wear protective gloves
Response	P301+P312 IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell P321 Specific treatment (see on this label) P330 Rinse mouth
Storage	P405 Store locked up
Disposal	P501 Dispose of contents/container in accordance with local/regional/national/international regulation

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	N/A
% By Weight	N/A
CAS#	850808-02-5
Molecular Weight	N/A
Chemical Formula	C ₂₀ H ₂₃ NO ₄ ·HCl·2H ₂ O
Synonym(s)	(5a)-17-(Cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride dihydrate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Naltrexone Hydrochloride Dihydrate	850808-02-5	100%	N/A	N/A

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Section 4: First-Aid Measures

Inhalation	Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation.
Skin Contact	Immediately wash with water and soap and rinse thoroughly
Eye Contact	Rinse opened eye for several minutes under running water
Ingestion	Immediately call a doctor.
Symptoms/Effects	
Acute	No further relevant information available.
Delayed	No further relevant information available.
Immediate Medical Attention	
No further relevant information available.	

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable Extinguishing Media

N/A

Products of Combustion

Hazardous combustion products are formed under fire conditions: carbon oxides, nitrogen oxides (NO_x), hydrogen chloride gas.

Firefighters Special Equipment and Precautions

N/A

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Wear protective equipment. Keep unprotected persons away. Environmental precautions: Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water. Methods and material for containment and cleaning up: Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

Section 7: Handling and Storage

Precautions for safe handling: Keep receptacles tightly sealed. Thorough dedusting. Ensure good ventilation/exhaustion at the workplace. Prevent formation of dust. Information about fire and explosion protection: no special measures required. Conditions for safe storage, including any incompatibilities: Requirements to be met by storerooms and receptacles: no special requirements. Information about storage in one common storage facility: not required. Protect from exposure to the light. Store in cool (below 27°C), dry conditions in well-sealed receptacles. 7.3 Specific end use(s) No further relevant information available.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	N/A
Engineering Controls	Components with limit values that require monitoring at the workplace: not required. The lists valid during the making were used as basis.
Personal Protection	General protective and hygienic measures Be sure to clean skin thoroughly after work and before breaks. Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Respiratory protection In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device dust mask type N95 (US) or type P1 (EN 143). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Hands protection The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves. Eye protection Safety glasses with side-shields conforming to EN 166. Skin and body protection Protective work clothing.

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Section 9: Physical and Chemical Properties

Appearance	White or almost white crystalline powder		
Odor	odourless		
Odor Threshold	No data available		
Melting Point	274-276C	pH	No data available
Freezing Point	No data available	Vapor Pressure	No data available
Boiling Point/Range	No data available	Vapor Density	No data available
Decomposition temperature	No data available	Viscosity	No data available
Partition Coefficient: n-octanol/water	No data available	Evaporation Rate	No data available
Flash Point	No data available	Autoignition temperature	No data available
Flammability	Product is not flammable	Flammability or Explosive Limits:	
		Lower	No data available
		Upper	No data available
Solubility(ies)	No data available		
Other	No data available		

Section 10: Stability and Reactivity

Reactivity	No data available.
Chemical Stability	Stable under recommended storage conditions. To avoid thermal decomposition do not overheat.
Hazardous Polymerization	No dangerous reactions known.
Conditions to Avoid	Moisture. Light.
Incompatible Materials	Bases.
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: carbon oxides, nitrogen oxides (NO _x), hydrogen chloride gas.

Section 11: Toxicological Information

RTECS	No data available.
Acute Toxicity	
LD50 Oral-rat	1450 mg/kg.
Skin Corrosion/Irritation	
No data available.	
Serious Eye Damage/Irritation	
No data available.	
Respiratory or Skin Sensitization	
No data available.	
Germ Cell Mutagenicity	
No data available.	
Carcinogenicity	
IARC (International Agency for Research on Cancer):	substance is not listed. NTP (National Toxicology Program): substance is not listed. OSHA-Ca (Occupational Safety & Health Administration): substance is not listed.
Reproductive Toxicity	
No data available.	
Routes of Entry	
No data available.	

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Symptoms Related to Exposure

No data available.

Potential Health Effects

Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Ingestion Harmful if swallowed. Skin May be harmful if absorbed through skin. May cause skin irritation. Eyes May cause eye irritation.

Target Organ(s) No data available.**Section 12: Ecological Information****Ecotoxicity**

No data available.

Persistence and Degradability

No data available.

Bioaccumulative Potential

No data available.

Mobility in Soil

No data available.

Other Adverse Effects

No data available.

Section 13: Disposal Considerations**Waste Disposal**

Must be specially treated adhering to official regulations. Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Disposal of Container

Disposal must be made according to official regulations

Other Considerations

No data available.

Section 14: Transport Information**DOT Classification**

UN-Number: Not applicable (Not dangerous goods). UN proper shipping name: Not applicable (Not dangerous goods). Transport hazard class(es): Not applicable (Not dangerous goods). Packing group: Not applicable (Not dangerous goods). Environmental hazards: None. Special precautions for user: Not applicable. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

Section 15: Regulatory Information**Regulations**

Directive 2012/18/EU Named dangerous substances - ANNEX I Substance is not listed. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

Other

No data available.

Section 16: Other Information

No data available.