

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

Section 1: Identification

Naloxone Hydrochloride USP Dihydrate **Product Name**

Not available. **Commercial Name**

Product Use Medication: Antagonist to Narcotics.

Not available. **Restrictions On Use**

30-3335 **Product Code**

PCCA Company In case of emergency contact:

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

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute Toxicity (Oral) Category 4 Skin Sensitizer Category 1

CFR 1910.1200

Signal Word WARNING

Harmful if swallowed. May cause allergic skin reaction Hazard Statement(s)

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Avoid breathing dust. Use only outdoors or in a well-ventilated area. Do not eat, drink or smoke when

using this product. Wash hands thoroughly after handling. Dust accumulation from this product may

CHEMTREC (24hr) 1-800-424-9300

present an explosion hazard in the presence of an ignition source.

If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to Response

fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

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

Dispose of contents/container in accordance with local/regional/national/international regulations **Disposal**

Section 3: Composition/Information on Ingredients

Mixture Substance/Mixture

Naloxone Hydrochloride USP Dihydrate and water Components

80 - 90 and 20 - 40 % By Weight CAS# 51481-60-8 and 7732-

399.87 g/mole Molecular Weight

C19-H21-N-O4.HCI-2H2O **Chemical Formula** Naloxon Hydrochloride; Allylnoroxymorphone Hydrochloride

Mixtures

Synonym(s)

Name CAS# % by Weight TLV/PEL LC50/LD50 51481-60-8 80-90 Naloxone Hydrochloride USP Dihydrate Water 7732-18-5 20-40

(Revision Date 2/25) Page 1 of 6



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

Section 4: First-Aid Measures

Inhalation Do not breathe dust. Move to fresh air and get medical attention.

Skin Contact After contact with skin, wash immediately with plenty of water. Immediately remove contaminated clothing

and shoes. Wash contaminated clothing before reuse. Seek m edical attention if symptoms appear.

Eye Contact Flush eye with water for 15 minutes. In the case of eye irritation see a physician.

Ingestion Immediate medical attention is required.

Symptoms/Effects

Acute Not available Delayed Not available.

Immediate Medical Attention

Not available.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Use water spray, foam, or dry chemical.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Carbon oxides, nitrogen oxides (NOx)

Firefighters Special Equipment and Precautions

Wear a self-contained breathing apparatus and full protective gear. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Section 6: Accidental Release Measures

Personal precautions: Wear appropriate eye, skin, respiratory protection, disposable dust impervious suit and shoe covers. Avoid dust formation. Environmental precautions: Do not allow material to contaminate ground water system. Do not wash down sewers or waterways. Methods for cleaning up: Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. A designated HEPA vacuum can be used as an alternative cleaning method for large spills of powder. All waste must be placed in a sealable, properly labeled wast e disposal bag. Material must be disposed of as hazardous drug waste.

Section 7: Handling and Storage

Handling Technical measures/precautions: Use only in area provided with appropriate exhaust ventilation. Handle and store per labeled instructions. Safe handling advice: Wear safety glasses and gloves. Clean work surfaces at the end of each day. Storage Technical measures/storage conditions: Store and transport in sealed bags contained within rigid drums or appropriate closed containers in a manner that minimizes the potential for spillage or container damage. Incompatible products: No special restrictions on storage with other products.

Section 8: Exposure Controls/Personal Protection

Exposure Limits
Engineering Controls

Not available.

Ensure adequate ventilation. In laboratories, vented enclosures or fume hoods required when weighing, handling, or transferring small quantities of powders. Glove boxes should be used to handle gram quantities. In pilot or production facilities, use glove boxes or contained processes supplemented with

local exhaust at contaminant release points.

(Revision Date 2/25) Page 2 of 6



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

Personal Protection

Eye protection: Wear safety glasses with side-shields. Goggles recommended if potential exists for direct exposure to dust or splashes. Hand protection: Wear Nitrile gloves when handling powders. When handling solutions, wear chemical -resistant gloves appropriate for the solvent(s) making up the solution. Skin and body protection Wear disposable dust impervious protective suit and shoe covers. Respiratory protection: Respiratory protection dependent on airborne exposures. When handling small quantities, use a respirator equipped with filters approved for dusts, mists, fumes and radionuclides (HEPA/N100 or in EU ABEK-P3). When handling large quantities, use powered air-purifying respirators equipped with HEPA filters or air - supplied hood, helmet or hard cap. Supplied air respirator required in the absence of effective local exhaust ventilation for control of airborne dusts.

(Revision Date 2/25) Page 3 of 6





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

Section 9: Physical and Chemical Properties

Appearance White to off-white powder Solid.

Odor Not available.
Odor Threshold Not available.

127 C Not available. **Melting Point** pН **Freezing Point** Not available. **Vapor Pressure** Not available. Not available. Not available. **Boiling Point/Range Vapor Density** Not available. Not available. **Decomposition temperature Viscosity Partition Coefficient:** Not available. **Evaporation Rate** Not available.

n-octanol/water

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 Not available.

Section 10: Stability and Reactivity

Reactivity Not available.

Chemical Stability Not available.

Hazardous PolymerizationHazardous polymerization will not occur.Conditions to AvoidKeep away from heat and sources of ignition

Incompatible Materials Not available.

Hazardous Decomposition Products Not available

Section 11: Toxicological Information

RTECS Not available.

Acute Toxicity

LD50 Oral Mouse (m) (mg/kg): Not determined LD50 Oral Dog (f) (mg/kg): Not determined LD50 Oral Dog (m) (mg/kg): Not determined LD50 Oral Rat (f) (mg/kg):Not determined LD50 Oral Rat (m) (mg/kg):Not determined LD50 Oral Mouse (f) (mg/kg):

Not determined

Skin Corrosion/Irritation

Not available.

Serious Eye Damage/Irritation

Not available.

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive Toxicity

Not available.

Routes of Entry

Eye. Skin. Inhalation.

(Revision Date 2/25) Page 4 of 6



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

Symptoms Related to Exposure

Not available.

Potential Health Effects

Not available.

Target Organ(s) Central Nervous System

Section 12: Ecological Information

Ecotoxicity

Not available.

Persistance and Degradability

Not available.

Bioaccumulative Potential

Not available.

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations

Waste Disposal

Waste from residues / unused products: Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.

Disposal of Container

Waste disposal must be in accordance with a ppropriate US, Federal, State and International regulations.

Other Considerations

Not available.

Section 14: Transport Information

DOT Classification

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information

Regulations

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. Drug Enforcement Administration (DEA). Ust 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) Not regulated DEA Essential Chemical Code Number, Not regulated Drug Enforcement Administration (DEA). Ust 1 & 2 Exempt Chemical Mbdures (21 CFR 1310.12(c)) Not regulated DEA Exempt Chemical Mixtures Code Number Not regulated 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 Section 302 extremely No hazardous substance Section 311 hazardous No chemical Inventory status Country(s) or region Inventory name On Inventory (yes/no). Australia Australian Inventory of Chemical Substances (AICS) Yes 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 No 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 New Zealand New Zealand Inventory Yes 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) State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

(Revision Date 2/25) Page 5 of 6





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

Other

US federal 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 - No Fire Hazard - Yes 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 On inventory (yes/no)* Australia Australia Inventory of Chemical Substances (AICS) Yes 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 No 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 New Zealand New Zealand Inventory Yes 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).

Section 16: Other Information

Disclaimer Mallinckrodt provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

(Revision Date 2/25)

Page 6 of 6