

Safety Data Sheet



1. Identification

Product Identifier	Naltrexone Hydrochloride	
Other means of identification		
Internal item number	82393-0111 82393-0404 82393-0405	
CAS number	16676-29-2	
Chemical name	17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride	
Relevant use and restrictions:	No further information available.	
Application of substance:	Active pharmaceutical ingredient.	
Manufacturer/Supplier information		
Company name	Pharma Source Direct	
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112	
Website	www.pharmasd.com	
Emergency phone number	Infotrac: 1-800-535-5053	

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Acute toxicity, oral	Category 4
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified	
OSHA defined hazards	Not classified	
Label elements		



Signal word	Warning
Hazard statement	Harmful if swallowed. May cause drowsiness or dizziness.
Precautionary statement	
Prevention	Wash thoroughly after handling. Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area.
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. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Safety Data Sheet



Version: 2.0
Issued: 06 Mar 2024

Disposal	Dispose of contents/container in accordance with local/regional/national/ international regulations.
Hazards not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/Information on Ingredients

Substance	Common name and synonyms	CAS number	%
Chemical name			
Naltrexone Hydrochloride	17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride	16676-29-2	100

4. First-aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Narcotic effects. Pharmacologically active material. Occupational exposure may cause physiological effects
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General Information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.

Safety Data Sheet



Version: 2.0
Issued: 06 Mar 2024

Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s)
Biological limit values	No biological exposure limits noted for the ingredient(s)
Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Safety Data Sheet



Version: 2.0

Issued: 06 Mar 2024

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Procedures for any use or quantity should be determined after an appropriate assessment.

9. Physical and Chemical Properties

Appearance	Appearance descriptions are general information and not specific to any lot.
Physical state	Solid.
Form	Powder.
Color	Tan. Off-white.
Odor	Almost odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	334.4 - 338 °F (168 - 170 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.

Safety Data Sheet



Version: 2.0
Issued: 06 Mar 2024

Solubility(ies)	
Solubility (water)	Insoluble
Solubility (other)	Ethanol: Soluble.
Partition coefficient (n-octanol/water)	0.534
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Noroxymorphone derivative.
Molecular formula	C ₂₀ H ₂₃ NO ₄ .ClH
Molecular weight	377.86
Oxidizing properties	Not oxidizing

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.
Possibility of hazardous reactions	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 _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Information on likely routes of exposure

Inhalation	May cause drowsiness and dizziness.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Gastrointestinal disturbances. Loss of appetite. Cramps. Tiredness. Headache. Dizziness. Nervousness. Difficulty sleeping. Joint pain. Muscle pain. Sore throat. Tremor. Seizures.

Information on toxicological effects

Acute toxicity	Harmful if swallowed.
Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.
Respiratory or skin sensitization	
Respiratory sensitization	Knowledge about health hazard is incomplete.

Safety Data Sheet



Version: 2.0

Issued: 06 Mar 2024

Skin sensitization Knowledge about health hazard is incomplete.
Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames assay
 Result: Negative.
 Micronucleus test
 Result: Negative.
 Species: Mouse
 Mutagenicity, CHO cell sister chromatid exchange assay
 Result: Negative.
 Mutagenicity, Drosophila recessive lethal frequency assay
 Result: Positive.
 Mutagenicity, Heritable translocation assay
 Result: Negative.
 Mutagenicity, Mouse lymphoma gene mutation assay
 Result: Negative. Mutagenicity, Non-specific DNA damage in E. coli
 Result: Positive.

Carcinogenicity Knowledge about carcinogenicity is incomplete.
 In two-year studies in rats given naltrexone, there were small increases in the numbers of testicular mesotheliomas in males and tumors of vascular origin in both sexes. Only the incidence of vascular tumors in females (4%) exceeded the maximum (2%) reported in historical control groups. No evidence of carcinogenicity was observed in several other two-year studies in mice or rats receiving naltrexone.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete..

Reproductivity

100 mg/kg/day Reproduction test
 Result: Significant increase in pseudopregnancy and a decrease in pregnancy rates. No effect on male fertility.
 Species: Rat
 <= 200 mg/kg/day Reproduction test
 Result: No fetal changes or birth defects in the offspring of rats and rabbits at this dose.
 >= 30 mg/kg/day Reproduction test
 Result: Increase incidences of early fetal loss.
 Species: Rat

Specific target organ toxicity - single exposure Narcotic effects.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Safety Data Sheet



Version: 2.0
Issued: 06 Mar 2024

Further information

Pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	
Octanol/water partition coefficient log Kow	
0.534	
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

Safety Data Sheet



Version: 2.0
Issued: 06 Mar 2024

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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 regulated.

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

SARA 313 (TRI reporting)

Not regulated.

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.

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

Safety Data Sheet



Version: 2.0

Issued: 06 Mar 2024

Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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	No
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Unites 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).

16. Other Information

Disclaimer The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

Issue date 06 Mar 2024

Version 1.0

Issued by Pharma Source Direct – Quality Assurance