


**1. Identification**

<b>Product identifier</b>	<b>NALTREXONE HYDROCHLORIDE</b>
<b>Other means of identification</b>	
<b>SDS number</b>	NALID
<b>Item Code</b>	1459, 1460, 1477, 1479, 9749
<b>CAS number</b>	16676-29-2
<b>Synonyms</b>	17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride * Naltrexone Hydrochloride Analytical Research Standard-(FOR R&D USE ONLY)
<b>Recommended use</b>	Medication: Antagonist to Narcotics.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company name</b>	SpecGx LLC
<b>Address</b>	385 Marshall Ave Webster Groves, MO 63119
<b>E-mail</b>	SpecGx-SDS@mnk.com
<b>Customer Service</b>	1-800-895-9048 (USA, Canada) 1-314-654-2000 (Worldwide)
<b>24 Hour Emergency</b>	CHEMTREC: 1-800-424-9300 (USA, Canada)

**2. Hazard(s) identification**

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
<b>Signal word</b>	Warning	
<b>Hazard statement</b>	Harmful if swallowed. May cause drowsiness or dizziness. Suspected of damaging fertility or the unborn child.	
<b>Precautionary statement</b>		
<b>Prevention</b>	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.	
<b>Response</b>	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.	
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

### 3. Composition/information on ingredients

#### Substances

Chemical name	Common name and synonyms	CAS number	%
NALTREXONE HYDROCHLORIDE	17-(cyclopropylmethyl)-4,5-epoxy-3, 14 dihydroxy-morphinan-6-one hydrochloride Naltrexone Hydrochloride Analytical Research Standard-(FOR R&D USE ONLY)	16676-29-2	100

**Composition comments** All concentrations are in percent by weight.

### 4. First-aid measures

<b>Inhalation</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>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</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/effects, acute and delayed</b>	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
<b>General information</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.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed such as: Carbon oxides. Nitrogen Oxides. Hydrogen Chloride (HCl).
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials. Follow handling guidance appropriate for OEB-2 compounds, (see section 7).
<b>General fire hazards</b>	Material will burn in a fire.

### 6. Accidental release measures

<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).
--	---

**Methods and materials for containment and cleaning up**

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.

**Environmental precautions**

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.

**7. Handling and storage****Precautions for safe handling**

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.

**Conditions for safe storage, including any incompatibilities**

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).

**Further information**

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.

\*OEB -SpecGx LLC Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

**8. Exposure controls/personal protection****Occupational exposure limits**

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.

SpecGx LLC Material	Type	Value	Form
NALTREXONE HYDROCHLORIDE (CAS 16676-29-2)	OEG	50 µg/m3	8-hour time-weighted average
	STEG	500 µg/m3	15-minute average
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Exposure guidelines	NALTREXONE HYDROCHLORIDE falls within Mallinckrodt Occupational Exposure Band 2B (OEB 2B) covering the 8-hour time-weighted average range >10 - 100 µg/m³. Short-term Exposure Guideline (STEG), if listed, is the Mallinckrodt value for a 15-minute exposure time.		
Appropriate 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.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Chemical goggles are recommended.		
Skin protection			
Hand protection	Wear appropriate chemical resistant gloves. Nitrile or butyl rubber gloves are recommended.		
Other	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.		
General hygiene considerations	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.		

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Off-white or White.

**Odor** Odorless.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**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	Not available.
Vapor density	Not available.
Relative density	1.3
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	1.84
Auto-ignition temperature	Not available.
Decomposition temperature	Decomposition to 270 °C.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Molecular formula	C20H23NO4.ClH
Molecular weight	377.86 g/mol
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 hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin.
Eye contact	Dust may irritate the eyes.
Ingestion	Harmful if swallowed.

**Symptoms related to the physical, chemical and toxicological characteristics**  
May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes.

### Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

Product	Species	Test Results
---------	---------	--------------

NALTREXONE HYDROCHLORIDE (CAS 16676-29-2)

#### Acute

##### Oral

LD50	Mouse	1100 mg/kg
	Rat	1450 mg/kg

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitization

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

**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.

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

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.
<b>Further information</b>	<p>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.</p> <p>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 dependant on opioids.</p> <p>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.</p>

## 12. Ecological information

<b>Ecotoxicity</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>Bioaccumulative potential</b>	
<b>Partition coefficient n-octanol / water (log Kow)</b>	
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.

## 13. Disposal considerations

<b>Disposal instructions</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>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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.

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

## 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.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

### US federal regulations

**Toxic Substances Control Act (TSCA)** This substance is not on the TSCA 8(b) inventory or is designated "inactive".

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Acute toxicity (any route of exposure)  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)

### 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 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)	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

Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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).

## 16. Other information, including date of preparation or last revision

Issue date	04-06-2015
Revision date	02-04-2020
Version #	08
Disclaimer	SpecGx LLC 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. SpecGx LLC 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, SpecGx LLC WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.
Revision information	Toxicological Information: Toxicological Data