

## SAFETY DATA SHEET

Preparation Date: 10/3/2019

Revision date Not Applicable

Revision Number: Not Applicable

### 1. IDENTIFICATION

**Product identifier**

**Product code:** N4022  
**Product Name:** Naltrexone Hydrochloride, USP

**Other means of identification**

**Synonyms:** Morphinan-6-one, 17-(cyclopropylmethyl)-4,5-alpha-epoxy-3,14-dihydroxy-, hydrochloride  
 17-(Cyclopropylmethyl)-4,5-alpha-epoxy-3,14-dihydroxy-morphinan-6-one hydrochloride  
 N-Cyclopropylmethyl-noroxymorphone hydrochloride  
 Morphinan-6-one, 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-, hydrochloride, (5-alpha)-

**CAS #:** 16676-29-2  
**RTECS #** QD2160000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)  
 Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
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**Label elements**

<b>Warning</b>
<b>Hazard statements</b> Harmful if swallowed



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product

IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell  
Rinse mouth

**Precautionary Statements - Disposal**

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Naltrexone Hydrochloride	16676-29-2	100

**4. FIRST AID MEASURES**

**First aid measures**

- General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
- Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
- Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
- Inhalation:** Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.
- Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

- Symptoms**
- May cause eye/skin/respiratory tract irritation
  - May cause mydriasis (dilated pupils)
  - May affect the liver
  - May affect the cardiovascular system
  - Cardiac arrhythmias
  - Heart palpitations
  - Hypotension

Hypertension  
May cause gastrointestinal disturbances  
May cause digestive (gastrointestinal) tract irritation  
May cause abdominal pain, nausea, vomiting, diarrhea  
May cause constipation  
May cause salivation  
Excessive sweating  
May cause loss of appetite  
Dyspnea (Difficulty breathing and shortness of breath)  
May cause muscle and joint pain  
Thirst  
Dryness of mouth  
May affect the urinary system  
Difficult/painful and/or frequent urination  
Central nervous system effects  
May cause depression  
Insomnia  
Headache  
May cause drowsiness or dizziness  
Anxiety  
Fatigue  
Hallucinations  
Confusion

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO<sub>x</sub>). hydrogen chloride gas.

**Specific hazards** May be combustible at high temperatures.

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid breathing dust. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

#### **Safe Handling Advice:**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep refrigerated. Store at 2-8 deg. C. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents  
Bases

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Naltrexone Hydrochloride	16676-29-2	None	None	None	None

##### **Canada**

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Naltrexone	16676-29-2	None	None	None	None

Hydrochloride					
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**Australia and Mexico**

Component	CAS No	Australia	Mexico
Naltrexone Hydrochloride	16676-29-2	None	None

**Appropriate engineering controls**

**Engineering measures to reduce exposure:** Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment**

**Personal Protective Equipment**

- Eye protection:** Goggles or Safety glasses with side-shields.
- Skin and body protection:** Chemical resistant apron  
Long sleeved clothing  
Gloves
- Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> White. Off-white.
<b>Odor:</b> Odorless.	<b>Taste</b> Bitter.	<b>Formula</b> C20H23NO4.HCl.2H2O
<b>Molecular/Formula weight (g/mole):</b> 413.90	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 274-276 °C (525.2-528.8 °F)	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Soluble in Water  
Slightly soluble in alcohol  
Practically insoluble in Dichloromethane

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents  
Reactive with bases

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:**  
Oxidizing agents  
Bases

**Hazardous decomposition products:** Products of Thermal Decomposition: Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Hydrogen chloride gas.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Naltrexone Hydrochloride

CAS No 16676-29-2

**LD50/oral/rat = 1450 mg/kg Oral LD50 Rat**

**LD50/oral/mouse = 1100 mg/kg**

**LD50/dermal/rabbit = No information available**

**LD50/dermal/rat = No information available**

**LC50/inhalation/rat = No information available**

**LC50/inhalation/mouse = No information available**

Other LD50 or LC50 information = 1490 mg/kg oral LD50 Guinea pig; 3000 mg/kg oral LD50 Monkey

## Product Information

### LD50/oral/rat =

Value - Acute Toxicity = 1450 mg/kg

### LD50/oral/mouse =

Value - Acute Tox = 1100 mg/kg

### LD50/dermal/rabbit

Value - Acute Toxicity = No information available

### LD50/dermal/rat

VALUE - Acute Tox = No information available

### LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

### LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

## Symptoms

### Skin Contact:

May cause skin irritation.

### Eye Contact:

May cause eye irritation.

### Inhalation

May cause irritation of respiratory tract.

### Ingestion

Harmful if swallowed. May cause digestive (gastrointestinal) tract irritation. May cause dry mouth, thirst. May cause gastrointestinal disturbances. May cause abdominal pain, nausea, vomiting, diarrhea. May cause constipation. May cause flatulence. May cause salivation. May cause excessive sweating. May cause decreased appetite or anorexia. May cause mydriasis (dilated pupils). May affect eyes (pupillary constriction). May affect the cardiovascular system (cardiac arrhythmias). May affect the cardiovascular system (hypotension or hypertension, tachycardia). May affect the cardiovascular system (palpitations). May affect behavior/central nervous system (lethargy, fatigue). May also cause anxiety and stress. May affect behavior/central nervous system (lightheadedness, dizziness). It may affect behavior/central nervous system (drowsiness). May affect behavior/central nervous system (somnolence, tremor). May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (hallucinations, insomnia). May cause headache. May affect behavior/central nervous system (convulsions/seizures). May cause joint and muscle pain. May affect the kidneys. May cause renal failure. May affect liver. May affect respiration (dyspnea - difficulty breathing and shortness of breath; hyperventilation). May cause tinnitus. May cause skin rash, redness or itching. May cause painful or difficult urination. May cause increase in urinary frequency. May cause nasal congestion.

### Ingestion:

May cause runny nose, depression, paranoia, restlessness, disorientation, nightmares and bad dreams.

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** Prolonged or repeated ingestion may affect the liver. Prolonged or repeated ingestion may affect behavior/central nervous system. Prolonged or repeated ingestion may cause change in sexual interest/ability, and impotence. Prolonged or repeated ingestion may cause increased or decreased sexual interest.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Naltrexone Hydrochloride	16676-29-2	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available

**Developmental Effects:** No information available

**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target Organs:** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility in soil** No information available

**Other adverse effects** No information available.

**13. DISPOSAL CONSIDERATIONS**



## Disposal Methods

### **Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

### **Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Naltrexone Hydrochloride	16676-29-2	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

### TDG (Canada)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

### ADR

**UN Number** Not regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

### IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

### RID

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available

**Subsidiary Risk:** No information available  
**Packing group:** No information available

**ICAO (air)**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN Number:** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es):** No information available  
**Subsidiary Risk:** No information available  
**Packing group:** No information available  
**Precautionary Statements - Response:** No information available  
**Special Provisions:** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Naltrexone Hydrochloride	16676-29-2	Not Listed	Not present	Not present	Not present	Not listed	Not listed	Present 240-723-0

**U.S. Regulations**

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Naltrexone Hydrochloride	16676-29-2	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Naltrexone Hydrochloride	16676-29-2	None	None	None	None	None

**U.S. TSCA**

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules	TSCA 8(d) -Health and Safety Reporting

		<b>(SNURS)</b>	
Naltrexone Hydrochloride	16676-29-2	Not Applicable	Not Applicable

**Canada**

**WHIMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has not been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

**DSL/NDSL**

Component	CAS No	Canada (DSL)	Canada (NDSL)
Naltrexone Hydrochloride	16676-29-2	Not Listed	Not Listed

<b>Component</b>	<b>CAS No</b>	<b>CEPA Schedule I - Toxic Substances</b>
Naltrexone Hydrochloride	16676-29-2	Not listed
<b>Component</b>	<b>CAS No</b>	<b>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</b>
Naltrexone Hydrochloride	16676-29-2	Not listed

**EU Classification**

**EU GHS - SV - CLP 1272/2008**

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Naltrexone Hydrochloride	16676-29-2	

**EU - CLP (1272/2008)**

**R-phrase(s)**

R22 - Harmful if swallowed

**S -phrase(s)**

S46 - If swallowed, seek medical advice immediately and show this container or label

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Naltrexone Hydrochloride	16676-29-2		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC**

**Indication of danger:**

Xn - Harmful

Xn



## 16. OTHER INFORMATION

**Preparation Date:** 10/3/2019  
**Revision date** Not Applicable  
**Prepared by:** Sonia Owen

**Disclaimer:** All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**