

Scientific Documentation

Naloxone Hydrochloride, Dihydrate, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Naloxone Hydrochloride, Dihydrate, USP (N1231)

Item Number	N1231
Item	Naloxone Hydrochloride, Dihydrate, USP
CAS Number	51481-60-8
Molecular Formula	$C_{19}H_{21}NO_4 \cdot HCl \cdot 2H_2O$
Molecular Weight	399.87
MDL Number	
Synonyms	17-Allyl-6-deoxy-7,8-dihydro-14-hydroxy-6-oxo-17-normorphine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	100.5 %
SPECIFIC ROTATION $[\alpha]_D$	-170° to -181°	
CHLORIDE CONTENT (DRIED BASIS)	9.54	9.94 %
NOROXYMORPHONE HCl AND OTHER[nIMPURITIES]		1.0 %
LOSS ON DRYING		11.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	N1231	Lot Number	2LD0178
Item	Naloxone Hydrochloride, Dihydrate, USP	Manufacturer Lot	6089339
CAS Number	51481-60-8	Manufacturer Code	4772
Molecular Formula	C ₁₉ H ₂₁ NO ₄ •HCl•2H ₂ O	Molecular Weight	399.87

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	100.5 %	98.2%
SPECIFIC ROTATION [α] _D	-170° to -181°		-177°
CHLORIDE CONTENT (DRIED BASIS)	9.54	9.94 %	9.71%
NOROXYMORPHONE HCl AND OTHER IMPURITIES		1.0 %	<0.05% (M)
LOSS ON DRYING		11.0 %	6.0%
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT(M)
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
RETEST DATE			28-FEB-2025
DATE OF MANUFACTURE			01-MAR-2020
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		. (M)
CLASS 2 (solvent) / ACETONITRILE			<410 PPM
CLASS 2 (solvent) / N,N-DIMETHYLACETAMIDE			<1090 PPM
CLASS 3 (solvent) / ACETONE			<5000 PPM
CLASS 3 (solvent) / 1-BUTANOL			<5000 PPM
CLASS 3 (solvent) / ETHANOL			<5000 PPM
CLASS 3 (solvent) / ISOBUTYL ACETATE			<5000 PPM
CLASS 3 (solvent) / 1-PROPANOL			<5000 PPM
CLASS 3 (solvent) / 2-PROPANOL			<5000 PPM

TEST	SPECIFICATION		RESULT
	MIN	MAX	
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

BPATEL
Bhargavi Patel
10-MAY-22 13:27:27

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
10-MAY-22 13:40:07

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Pharmaron Manufacturing Services (UK) Ltd at Windmill Industrial Estate, Shotton Lane, Cramlington, Northumberland NE23 3JL, United Kingdom (GBR). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 4/1/2016

Revision Date: 8/27/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: N1231
Product Name: NALOXONE HYDROCHLORIDE, DIHYDRATE, USP

Other means of identification

Synonyms: 17-Allyl-6-deoxy-7,8-dihydro-6-oxo-17-normorphine Hydrochloride Dihydrate
 17-Allyl-4,5-alpha-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride dihydrate
 I-N-Allyl-14-hydroxynordihydromorphinone hydrochloride dihydrate
CAS #: 51481-60-8
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: In pharmaceuticals. Medication. Drug.
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: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to 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
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Harmful if swallowed
 Causes serious eye irritation

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 HYDROCHLORIDE, DIHYDRATE, USP

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Causes skin irritation
May cause respiratory irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Do not eat, drink or smoke when using this product
Wear respiratory protection
Wear eye/face protection
Wear protective gloves
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wash face, hands and any exposed skin thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

Precautionary Statements - Response

Call a POISON CENTER or doctor/physician if you feel unwell
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF ON SKIN: Wash with plenty of water
Wash contaminated clothing before reuse
If skin irritation or rash occurs: Get medical advice/attention
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
IF SWALLOWED:
Rinse mouth

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Naloxone Hydrochloride, Dihydrate	51481-60-8	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

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shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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 allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Ingestion may cause vomiting and nausea
Cardiac arrhythmias
Weak, rapid pulse or rapid heart rate (Tachycardia)
Hypertension
Irritability
Tremors
Seizures
Convulsions
Headache
Sweating
May cause difficulty swallowing
Dyspnea (Shortness of breath and difficulty breathing)
May cause pulmonary edema

Indication of any immediate medical attention and special treatment needed

Notes to Physician:

Treat symptomatically. Oxygen, if needed.

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 (CO₂). 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.
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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Use personal protective equipment. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers.

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. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Ensure adequate ventilation. 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. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Naloxone Hydrochloride, Dihydrate	51481-60-8	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British	Canada - Ontario	Canada - Quebec
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			Columbia		
Naloxone Hydrochloride, Dihydrate	51481-60-8	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Naloxone Hydrochloride, Dihydrate	51481-60-8	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

Skin and body protection: Chemical resistant protective suit
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

Physical state:

Solid

Appearance:

Crystalline powder.

Color:

White. Off-white.

Odor:

Odorless.

Taste

No information available.

Formula:

C₁₉H₂₁NO₄.HCl.2H₂O

Molecular/Formula weight (g/mole):

399-87

Flammability:

No information available

Flashpoint (°C/°F):

No information available.

Flash Point Tested according to:

Not available

Autoignition Temperature (°C/°F):

No information available

Lower Explosion Limit (%):

No information available

Upper Explosion Limit (%):

No information available

Melting point/range(°C/°F):

182 °C/360 °F

Decomposition temperature(°C/°F):

No information available

Boiling point/range(°C/°F):

No information available

Bulk density:

No information available

Density (g/cm³):

No information available

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Specific gravity:
No information available

pH:
No information available

Vapor pressure @ 20°C (kPa):
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):**
log Pow: 6.377

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Soluble in Water
Practically insoluble in Ether

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon oxides. When heated to decomposition it emits toxic fumes. Nitrogen oxides (NOx).

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

Naloxone Hydrochloride, Dihydrate

CAS-No. 51481-60-8

LD50/oral/rat = No information available

LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

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Other LD50 or LC50 information = >1000 mg/kg oral LD50 Rat (for Naloxone HCl anhydrous (CAS no. 357-08-4)
>1000 mg/kg oral LD50 Mouse (for Naloxone HCl anhydrous (CAS no. 357-08-4)

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = 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 Ingestion may cause nausea, vomiting. May cause excessive sweating. May cause difficulty swallowing. May affect respiration (dyspnea - difficulty breathing and shortness of breath). May affect respiration (acute pulmonary edema). May cause headache. May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (cardiac arrhythmias). It may affect cardiovascular system (hypertension). May affect behavior/central nervous system (confusion, irritability, tremor). May affect behavior/central nervous system (convulsions/seizures).

Aspiration hazard No information available.

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

Chronic Toxicity Skin: Sensitizer. May cause allergic skin reaction (allergic contact dermatitis). Prolonged or repeated inhalation may cause allergic reaction.

Sensitization: May cause sensitization by inhalation and skin contact.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Naloxone Hydrochloride, Dihydrate	51481-60-8	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 Respiratory system.
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: 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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Naloxone Hydrochloride, Dihydrate	51481-60-8	None	None	None	None

14. TRANSPORT INFORMATION

DOT

Product code: N1231

Product name: NALOXONE
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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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available

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

ICAO

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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
ERG Code:	No information available
Special Provisions	No information available

Product code: N1231

Product name: NALOXONE
HYDROCHLORIDE, DIHYDRATE, USP

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Naloxone Hydrochloride, Dihydrate	51481-60-8	Not Listed	Not present	Not present	Not present	Not present	Present	Not present

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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Naloxone Hydrochloride, Dihydrate	51481-60-8	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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
Naloxone Hydrochloride, Dihydrate	51481-60-8	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Naloxone Hydrochloride, Dihydrate	51481-60-8	Not Applicable	Not Applicable

Canada

WHMIS 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 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

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
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Product code: N1231

Product name: NALOXONE
HYDROCHLORIDE, DIHYDRATE, USP

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Naloxone Hydrochloride, Dihydrate	51481-60-8	Not Listed	Not Listed
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Components	CAS-No.	CEPA Schedule I - Toxic Substances
Naloxone Hydrochloride, Dihydrate	51481-60-8	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Naloxone Hydrochloride, Dihydrate	51481-60-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Naloxone Hydrochloride, Dihydrate	51481-60-8	

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed.

R36/38 - Irritating to eyes and skin.

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 - Wear suitable gloves.

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

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Naloxone Hydrochloride, Dihydrate	51481-60-8		No information	

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

Indication of danger:

Xn - Harmful.

Xi - Irritant.

Xn



Xi



16. OTHER INFORMATION

Preparation Date: 4/1/2016
Revision Date: 8/27/2018
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



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
N1231	Naloxone Hydrochloride, Dihydrate, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

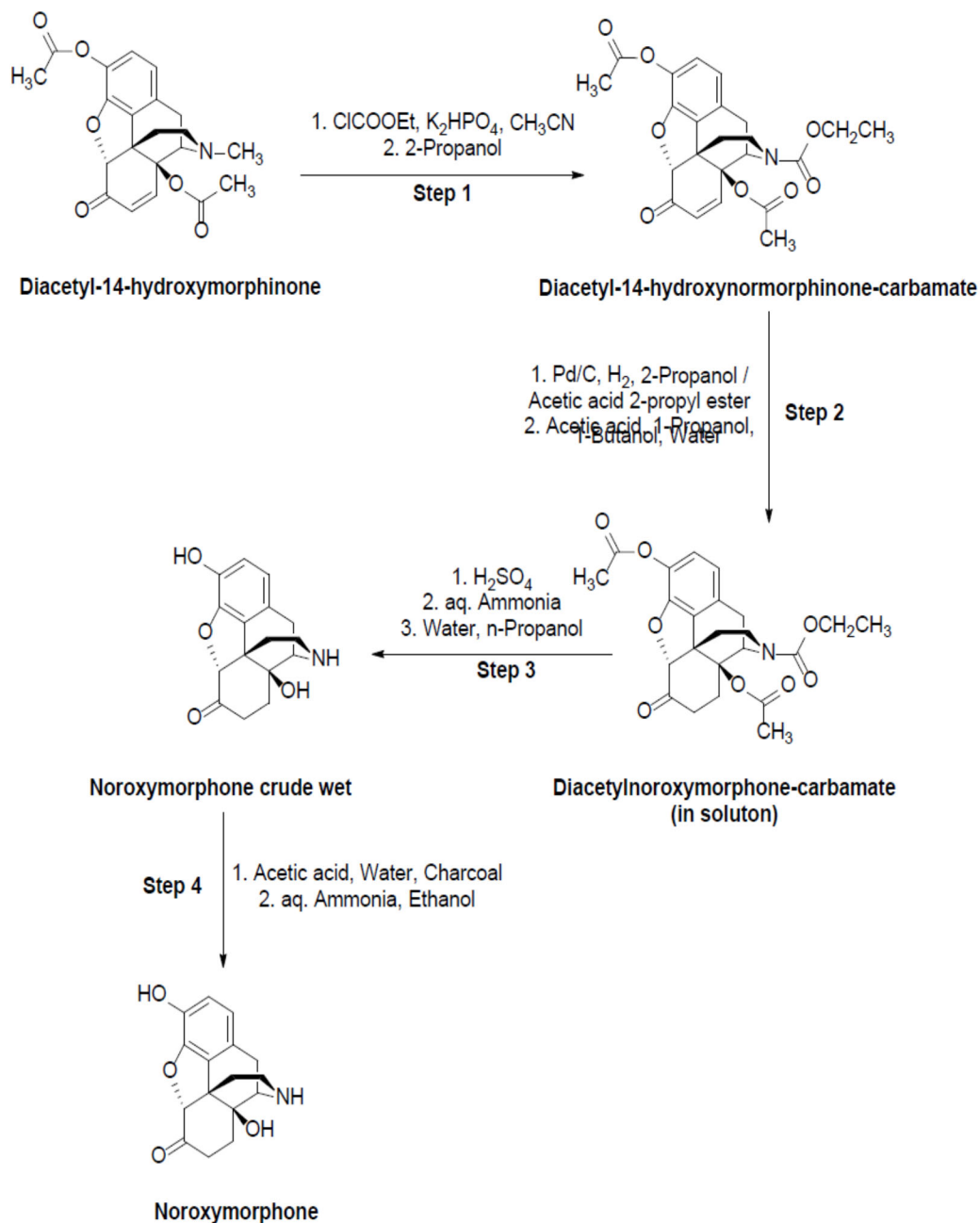
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Naloxone Hydrochloride, Dihydrate, USP (Cat# N1231)

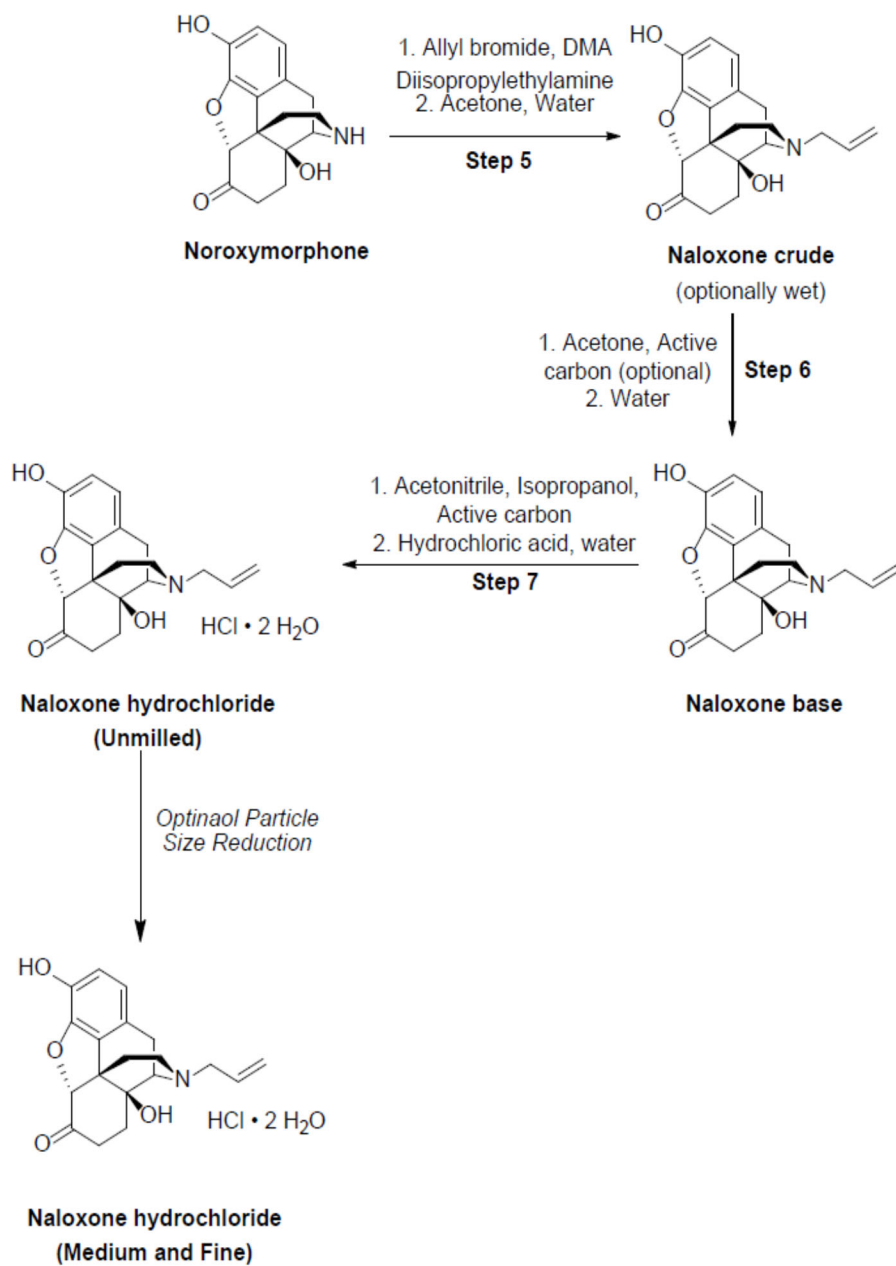


CORPORATE HEADQUARTERS

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WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

N1231, Naloxone Hydrochloride, Dihydrate, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Naloxone Hydrochloride, Dihydrate, USP (Cat# N1231)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Naloxone Hydrochloride, Dihydrate, USP (Cat# N1231)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Acetonitrile	2	< 410 ppm
<i>N,N</i> -Dimethylacetamide	2	< 1090 ppm
Acetone	3	< 5000 ppm
1-Butanol	3	< 5000 ppm
Ethanol	3	< 5000 ppm
Isobutyl Acetate	3	< 5000 ppm
1-Propanol	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

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Gardena, California 90248


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FAX 310.516.9843

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

Retest Date: 00-00-0000



DANGER

- Harmful if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation
- May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Do not eat, drink or smoke when using this product
- Wear respiratory protection, eye protection, face protection, protective gloves • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling
- Contaminated work clothing must not be allowed out of the workplace.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

N1231

Naloxone Hydrochloride

(17-Allyl-6-deoxy-7,8-dihydro-14-hydroxy-6-oxo-17-normorphine Hydrochloride)

Dihydrate, USP

CAS 51481-60-8

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

SIZ SY

$C_{19}H_{21}NO_4 \cdot HCl \cdot 2H_2O$ F.W. 399.87

Manufacturer/Supplier Code?

Manufacturer Lot Number?

Assay (Dried Basis) 98.0-100.5%

Specific Rotation, $[\alpha]_D^{25}$ -170° to -181°

Chloride Content (Dried Basis) 9.54-9.94%

MAXIMUM LIMITS

Noroxymorphone Hydrochloride and Other Impurities To pass test

Loss on Drying 11.0%

Elemental Impurities As reported

Residual Solvents To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

G 9/K3GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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