



# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 09/12/2024

Version: 2.0

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Naloxone Hydrochloride Injection, USP

#### 1.2. Intended Use of the Product

Bulk pharmaceutical product/mixture used to reverse CNS depression caused by opioid overdose, and post-operatively after use of opioids during surgery.

#### 1.3. Name, Address, and Telephone of the Responsible Party

##### Company

Endo USA Inc

870 Parkdale Rd

Rochester, MI 48307 USA

1-800-828-9393 (Phone)

1-201-829-9222 (Fax)

#### 1.4. Emergency Telephone Number

**Emergency Number** : VelocityEHS  
(800)255-3924 (North America)  
+1 (813)248-0585 (International)

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

##### GHS-US/CA Classification

Not classified

#### 2.2. Label Elements

##### GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

#### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

#### 2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	>97%	Not classified
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / hydrochloric acid	(CAS-No.) 7647-01-0	<1%	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT / sodium chloride	(CAS-No.) 7647-14-5	<1%	Not classified
Naloxaone hydrochloride	(-)-17-Allyl-4,5a-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride; naloxone hydrochloride.	(CAS-No.) 357-08-04	<1%	ATO4:H302

Full text of H-statements: see section 16

# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

\*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First-aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**Skin Contact:** Remove contaminated clothing. Wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Not expected to present a significant hazard under anticipated conditions of normal use.

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** May cause slight irritation to eyes.

**Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

#### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Not flammable. Use extinguishing media suitable for surrounding type of fire.

**Unsuitable Extinguishing Media:** None known.

#### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

#### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** None expected under normal conditions of use.

#### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

##### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

##### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

#### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a large spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

### 7.3. Specific End Use(s)

Bulk pharmaceutical product/mixture used to reverse CNS depression caused by opioid overdose, and post-operatively after use of opioids during surgery.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
USA OSHA	OSHA PEL (Ceiling)	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL C [ppm]	5 ppm

### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment:** Gloves. Protective clothing. Protective goggles.



**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical safety goggles.

**Skin and Body Protection:** Wear suitable protective clothing.

**Respiratory Protection:** If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

**Environmental Exposure Controls:** Avoid unnecessary release into the environment.

**Other Information:** When using, do not eat, drink or smoke.

# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear liquid
Odor	: Not determined
Odor Threshold	: No data available
pH	: 3.5 ± 0.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

#### 10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

#### 10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

#### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

#### 10.6. Hazardous Decomposition Products:

None expected under normal conditions of use.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on Toxicological Effects - Product

**Acute Toxicity (Oral):** Not classified (Based on available data, the classification criteria are not met)

**Acute Toxicity (Dermal):** Not classified (Based on available data, the classification criteria are not met)

**Acute Toxicity (Inhalation):** Not classified (Based on available data, the classification criteria are not met)

##### LD50 and LC50 Data:

No additional information available

**Skin Corrosion/Irritation:** Not classified (Based on available data, the classification criteria are not met)

pH: 3.0 – 4.0

**Eye Damage/Irritation:** Not classified (Based on available data, the classification criteria are not met)

pH: 3.0 – 4.0

**Respiratory or Skin Sensitization:** Not classified (Based on available data, the classification criteria are not met)

**Germ Cell Mutagenicity:** Not classified (Based on available data, the classification criteria are not met)

**Carcinogenicity:** Not classified (Based on available data, the classification criteria are not met)

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified (Based on available data, the classification criteria are not met)

**Reproductive Toxicity:** Not classified (Based on available data, the classification criteria are not met)

# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

**Specific Target Organ Toxicity (Single Exposure):** Not classified (Based on available data, the classification criteria are not met)

**Aspiration Hazard:** Not classified (Based on available data, the classification criteria are not met)

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 11.2. Information on Toxicological Effects - Ingredient(s)

#### LD50 and LC50 Data:

<b>Naloxone hydrochloride (CAS No.)-357-08-04</b>	
LD50 Oral Rat	1250 mg/kg
LD50 Intravenous Rat	109 mg/kg
LD50 Intravenous Mouse	150 mg/kg
<b>Hydrochloric acid (7647-01-0)</b>	
LD50 Dermal Rabbit	> 5010 mg/kg
<b>Sodium chloride (7647-14-5)</b>	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h)

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

<b>Hydrochloric acid (7647-01-0)</b>	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
<b>Sodium chloride (7647-14-5)</b>	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

### 12.2. Persistence and Degradability

<b>Naloxone Hydrochloride Injection, USP</b>	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

<b>Naloxone Hydrochloride Injection, USP</b>	
Bioaccumulative Potential	Not established.
<b>Sodium chloride (7647-14-5)</b>	
BCF Fish 1	(no bioaccumulation)

### 12.4. Mobility in Soil

<b>Naloxone Hydrochloride Injection, USP</b>	
Ecology - Soil	Leaches if exposed to water.

### 12.5. Other Adverse Effects

**Other Adverse Effects:** None known.

**Other Information:** Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste Treatment Methods:** Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer.

# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

**Additional Information:** Disposal through controlled incineration or authorized waste dump.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

### 14.1. In Accordance with DOT

Not regulated for transport

### 14.2. In Accordance with IMDG

Not regulated for transport

### 14.3. In Accordance with IATA

Not regulated for transport

### 14.4. In Accordance with TDG

Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
<b>CERCLA RQ</b>	5000 lb
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 lb (gas only)

<b>Sodium chloride (7647-14-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

### 15.2. US State Regulations

<b>Naloxone hydrochloride (CAS No.)-375-08-04</b>	
<b>State or local regulations: N/A</b>	
<b>Hydrochloric acid (7647-01-0)</b>	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	

### 15.3. Canadian Regulations

<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the Canadian DSL (Domestic Substances List)	
<b>Water (7732-18-5)</b>	
Listed on the Canadian DSL (Domestic Substances List)	

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest** : 05/31/2024

**Revision 1.0**

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

**GHS Full Text Phrases:**

Acute Tox. (Oral)	Acute toxicity (Oral) Category 4
H302	Harmful if swallowed

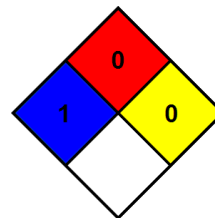
# Naloxone Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

H315	Causes skin irritation
H318	Causes serious eye damage

NFPA Health Hazard	: 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA Fire Hazard	: 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.
NFPA Reactivity Hazard	: 0 - Material that in themselves are normally stable, even under fire conditions.



*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*