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Version 1

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING****Product identifier****Product Name** NARCAN NALOXONE HCl NASAL SPRAY 4MG**Other means of identification****Product Code** 1745672**Synonyms** Narcan<sup>®</sup> (Naloxone HCl) Nasal Spray**Recommended use of the chemical and restrictions on use****Recommended Use** Opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Intended for immediate administration as emergency therapy in settings where opioids may be present.**Uses advised against** Only intranasal use.**Details of the supplier of the safety data sheet****Supplier Address**Emergent Devices Inc.  
401 Plymouth Road  
Suite 400  
Plymouth Meeting, Pennsylvania 19462**Emergency telephone number****Company Phone Number** 844-232-7811**Emergency Telephone** 888-483-9053**2. HAZARDS IDENTIFICATION****Classification****Health Hazards**

Not classified.

**Physical Hazards**

Not classified.

**OSHA Regulatory Status**

This product is not considered hazardous according to OSHA Hazard Communication Standard (29 CFR 1910.1200, Revision 3).

**Label elements****Emergency Overview****Appearance** - Clear to yellow**Physical state** - Liquid**Odor** - Odorless**Hazards not otherwise classified (HNOC)**

Naloxone Hydrochloride is a solution containing naloxone hydrochloride, a competitive antagonist of opioid receptors. Clinically, Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation, and hypotension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potent drug. Based on clinical use, possible target organs include the central nervous system and cardiovascular system.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3). Hydrochloric acid may be used to adjust the pH.

Chemical name	CAS No	Weight-% *
Naloxone Hydrochloride	51481-60-8	>3 - <5
Benzalkonium Chloride solution	8001-54-5	<0.025
Edetate Disodium	6381-92-6	0.2
Sodium chloride	7647-14-5	<0.8
Water for injection, USP	7732-18-5	<95

NOTE: \*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. FIRST AID MEASURES****Description of first aid measures**

<b>General Advice</b>	Take a copy of the Safety Data Sheet when going for medical treatment.
<b>Eye Contact</b>	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin Contact</b>	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
<b>Inhalation</b>	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. In case of inhalation, remove to fresh air. If not breathing, call 911 and provide artificial respiration. Do not use mouth-to-mouth method; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device if breathing is difficult. Seek emergency medical attention immediately.
<b>Ingestion</b>	Ingestion is not an anticipated route of occupational exposure. In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Self-Protection of the First Aider</b>	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

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

<b>Symptoms</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to Physicians</b>	Treat symptomatically.
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**5. FIRE-FIGHTING MEASURES****Suitable extinguishing media**

CO<sub>2</sub>, dry chemical, dry sand, alcohol-resistant foam, water spray.

**Unsuitable Extinguishing Media** None known.

**Hazardous Combustion Products**

Decomposition products may include the following materials: Carbon dioxide, Carbon monoxide, Nitrogen oxides, Halogenated compounds.

**Explosion data**

**Sensitivity to Mechanical Impact** Not sensitive.

**Sensitivity to Static Discharge** Not sensitive.

**Protective equipment and precautions for firefighters**

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**

Not applicable to consumer use. In an industrial setting, ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8 and follow handling guidance appropriate for the compound (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

**Environmental precautions****Environmental precautions**

Prevent product from entering drains.

**Methods and material for containment and cleaning up****Methods for Containment**

Contain spill if it can be done with minimal risk. Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean the affected area with soap and water.

**Methods for Cleaning Up**

Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

**7. HANDLING AND STORAGE****Precautions for safe handling****Advice on Safe Handling**

Handle in accordance with good industrial hygiene and safety practice. Take special precautions especially during withdrawal of needles from drug vials, drug transfers using syringes and needles or filter straws, and expulsion of air from drug-filled syringes.

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

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool, and well-ventilated area. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

**Incompatible Materials**

Oxidizing materials.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters****Exposure Guidelines**

This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

**Appropriate engineering controls****Engineering Controls**

Not normally required for routine, medical administration of this product. The health hazard risks of handling this material are dependent on factors such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Provide adequate ventilation where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

**Individual protection measures, such as personal protective equipment****Eye/Face Protection**

Not normally required for routine, medical administration of this product. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and Body Protection**

Not normally required for routine, medical administration of this product. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory Protection**

Respiratory protection is normally not needed during intended product use. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**General Hygiene Considerations**

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.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Physical state</b>	Liquid	<b>Odor</b>	Odorless
<b>Appearance</b>	Clear to yellow	<b>Odor Threshold</b>	Not available.
<b>Color</b>	Not available.		
<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks</u></b>	
<b>pH</b>	5.0		
<b>Melting point/freezing point</b>	Not available.		
<b>Boiling point/boiling range</b>	Not available.		
<b>Flash point</b>	Not available.		
<b>Evaporation rate</b>	Not available.		
<b>Flammability (solid, gas)</b>	Not available.		
<b>Flammability Limit in Air</b>			
Upper flammability limit:	Not available.		
Lower flammability limit:	Not available.		
<b>Vapor pressure</b>	Not available.		
<b>Vapor density</b>	Not available.		
<b>Specific Gravity</b>	Not available.		
<b>Water solubility</b>	Not available.		
<b>Solubility in other solvents</b>	Not available.		
<b>Partition coefficient</b>	Not available.		
<b>Autoignition temperature</b>	Not available.		
<b>Hyphen</b>	Not available.		
<b>Kinematic viscosity</b>	Not available.		
<b>Dynamic viscosity</b>	Not available.		
<b>Explosive Properties</b>	Not available.		

**Oxidizing Properties** Not available.

**Other information**

**Softening point** Not available.

**Molecular weight** Not available.

**VOC Content (%)** Not available.

**Density** Not available.

**Bulk density** Not available.

## 10. STABILITY AND REACTIVITY

**Reactivity**

Stable in normal conditions.

**Chemical stability**

Stable under normal conditions.

**Possibility of hazardous reactions**

None under normal processing.

**Hazardous Polymerization** No data available.

**Conditions to Avoid**

As a precautionary measure, keep away from strong oxidizers and acids.

**Incompatible materials**

Oxidizing materials.

**Hazardous decomposition products**

Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx) and hydrogen chloride.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Naloxone Hydrochloride	= 1,260 mg/kg (Rat)	-	-	109 mg/kg (Rat)
Sodium Chloride	= 3 g/kg (Rat)	-	>42 g/m3 (Rat) 1 hr	-
Benzalkonium Chloride	= 240 mg/kg (Rat)	= 1420 mg/kg (Rat)	-	-

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

**Irritation** Naloxone Hydrochloride is expected to be mildly irritating to the eyes.

**Sensitization** Naloxone Hydrochloride may produce an allergic reaction.

**Carcinogenicity** Carcinogenicity and mutagenicity studies have not been performed with naloxone hydrochloride. Not listed by IARC, NTP, or USOSHA.

**Reproductive Toxicity** Fertility was not impaired in reproductive studies in mice and rats. Teratogenic effects were not produced in the offspring of mice or hamsters treated during pregnancy with large doses of naloxone. Behavioral effects were reported in neonatal rats treated during pregnancy with large doses of naloxone. Endogenous opioids are important mediators of several neurologic functions, and this property has raised concerns that opioid antagonists may interfere with normal homeostatic mechanisms. A study to examine the possible role of opioids in the ovine fetal response to hypoxia did not show an adverse effect of naloxone. The NOAEL in a study of embryo fetal development in mice given subcutaneous naloxone was 10mg/kg/day. This was also the NOAEL in a study of pre and postnatal development in rats given subcutaneous naloxone. U.S. FDA Pregnancy Category B.

Genotoxicity	Genotoxic effects were produced in vitro but not in vivo (no other information is available). Positive in the Ames bacterial reverse mutation assay and in a chromosomal aberration assay. Negative in a CHO/HGPRT mammalian cell forward gene mutation assay. Negative in an in vivo study for chromosomal aberrations in the rat.
STOT - Single Exposure	Not available.
STOT - Repeated Exposure	Not available.
Aspiration Hazard	Not available.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Releases to the environment should be avoided.

### Persistence and degradability

Not available.

### Bioaccumulation

No available.

### Mobility

Not available.

### Other adverse effects

No available

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

Disposal of Wastes	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
Contaminated Packaging	Disposal should be in accordance with applicable regional, national, and local laws and regulations. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations. Do not reuse container/vial.
US EPA Waste Number	Not applicable.
California Hazardous Waste Codes	Code #311 - Pharmaceutical Waste

## 14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated.
Proper Shipping Name	Non-regulated.
Hazard Class	N/A
<u>TDG</u>	Not applicable.

<b><u>MEX</u></b>	Not applicable.
<b><u>ICAO (air)</u></b>	Not applicable.
<b><u>IATA</u></b> Proper Shipping Name	Not applicable. N/A
<b><u>IMDG</u></b> Hazard Class	Not applicable. N/A
<b><u>RID</u></b>	Not applicable.
<b><u>ADR</u></b>	Not applicable.
<b><u>ADN</u></b>	Not applicable.

## 15. REGULATORY INFORMATION

### **International Inventories**

<b>TSCA</b>	Contact supplier for inventory compliance status.
<b>DSL/NDSL</b>	Contact supplier for inventory compliance status.
<b>EINECS/ELINCS</b>	Contact supplier for inventory compliance status.
<b>ENCS</b>	Contact supplier for inventory compliance status.
<b>IECSC</b>	Contact supplier for inventory compliance status.
<b>KECL</b>	Contact supplier for inventory compliance status.
<b>PICCS</b>	Contact supplier for inventory compliance status.
<b>AICS</b>	Contact supplier for inventory compliance status.

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazard Categories**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**US State Right-to-know Regulation**

This product does not contain any substances regulated by state right-to-know regulations.

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable.

**16. OTHER INFORMATION**

Issue Date	17-Aug-2023
Revision Date	N/A
Revision Note	N/A

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**