

Safety Data Sheet

Narcan (Naloxone Hydrochloride) Nasal Spray

SDS Revision Date:

09/17/2015

1. Identification

1.1. Product identifier

Product Identity

Narcan (Naloxone Hydrochloride) Nasal Spray

Alternate Names

Chemical Formula C₁₉H₂₁NO₄ • HCl

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use

See Technical Data Sheet.

Application Method

See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name

Adapt Pharma Inc.,
100 Matsonford Road
Building 4, Suite 201
Radnor, PA 19087

Customer Service: Adapt Pharma Inc.,

Tel: +1-844-232-7811
Email: info@adaptpharma.com

2. Hazard(s) identification

2.1. Classification of the substance or mixture

No applicable GHS categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:

No GHS prevention statements

[Response]:

No GHS response statements

[Storage]:

No GHS storage statements

[Disposal]:

No GHS disposal statements

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3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Active Ingredient Name Naloxone Hydrochloride

Chemical Formula C₁₉H₂₁NO₄ • HCl

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, benzalkonium chloride, and sodium ethylenediaminetetraacetate. Hydrochloric acid may be used to adjust the pH.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Naloxone Hydrochloride CAS Number: 0051481-60-8	1 - 5	Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General

In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin

Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

4.2. Most important symptoms and effects, both acute and delayed

Overview

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.

Information on the absorption of this product via inhalation or skin contact is not available.
Avoid liquid aerosol generation and skin contact.

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5. Fire-fighting measures

5.1. Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: 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.

5.3. Advice for fire-fighters

None anticipated for this aqueous product.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

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 affected area with soap and water.

7. Handling and storage

7.1. Precautions for safe handling

No special handling required for hazard control under conditions of normal product use.

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Incompatible materials: No data available.

7.3. Specific end use(s)

No data available.

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8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0051481-60-8	Naloxone Hydrochloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0051481-60-8	Naloxone Hydrochloride	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. 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.

Eyes

Chemical safety glasses are recommended.

Skin

Protective gloves (e.g. latex or nitrile) recommended.

Engineering Controls

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.

Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

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9. Physical and chemical properties

Appearance	Clear colorless to slightly yellow aqueous Liquid
Odor	Odorless
Odor threshold	Not determined
pH	4.5
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	1.012/1.018
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. 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.

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11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Naloxone Hydrochloride - (51481-60-8)	No data available	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Naloxone Hydrochloride - (51481-60-8)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

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12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	Not Regulated
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): No

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Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

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