



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Naloxone Hydrochloride Nasal Solution (Nasal Spray) 4 mg/Spray, 2 mg/Spray

Synonym: 2Y2, 0K0, 64Q

Manufacturer Name: Padagis US LLC
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Code 335768

Email Address: EHS@padagis.com

Recommended use: Human drug – for emergency treatment of opioid overdose

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Naloxone Hydrochloride	51481-60-8	2-5%
Water	7732-18-5	Proprietary
Benzalkonium Chloride	121-54-0	<0.1%
Edetate Disodium Dihydrate	6381-92-6	Proprietary
Sodium Chloride	7647-14-5	Proprietary
Hydrochloric Acid	7647-01-0	pH adj

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Get medical attention if irritation or other symptoms persist.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention advice.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. May cause mild skin irritation. Ingestion may cause gastrointestinal distress and effects similar to clinical use. Adverse reaction from clinical use includes increased blood pressure, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal congestion, nasal inflammation, rhinalgia and xeroderma.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any extinguishing media appropriate for the fire situation.

Specific hazards arising from the chemical: Product is not flammable or combustible.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid eye contact. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Naloxone Hydrochloride	10-100 ug/m ³ TWA PERRIGO OEB3
Benzalkonium Chloride	None Established
Edetate Disodium Dihydrate	None Established
Sodium Chloride	None Established
Hydrochloric Acid	2 ppm Ceiling ACGIH TLV 5 ppm Ceiling OSHA PEL

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended if needed to avoid contact.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Clear, colorless to yellowish solution

Odor: Odorless

Odor threshold: Not applicable	pH: 3.5-5.5
Melting point/freezing point: No data available	Boiling Point: No data available
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: ~1.0	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not applicable
Decomposition temperature: No data available	Viscosity: Same as water

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: None known.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract. Adverse reaction from clinical use includes increased blood pressure, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal congestion, nasal inflammation, rhinalgia and xeroderma.

Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea and effects similar to clinical use described above..

Skin contact: No adverse effects are expected. Minor irritation is possible.

Eye contact: Contact may cause irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not skin sensitizers.

Germ Cell Mutagenicity: Components are not germ cell mutagens. Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study.

Reproductive Toxicity: Components are not reproductive toxins. Naloxone hydrochloride was administered subcutaneously to rats and mice at doses up to 10 mg/kg/day with no embryotoxic or teratogenic effects. Male and female rats were treated with naloxone at 2 and 10 mg/kg with no effects on fertility.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Components are not acutely toxic.

Naloxone Hydrochloride: LD50 oral rat >1000 mg; LD50 oral mouse >1000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

Naloxone Hydrochloride Nasal Solution (Nasal Spray) 4 mg/Spray, 2 mg/Spray
2Y2, 0K0

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: October 8, 2017

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).