

SDS Identifier: Naloxone Hydrochloride Injection USP

**SECTION 1: IDENTIFICATION**

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**Product Identifier**

**Product Name:** Naloxone Hydrochloride Injection USP, Naloxone Injectable  
**Other Name:** Naloxone Hydrochloride Injection 0.4 mg/mL  
**Chemical Family:** Mixture

**Product Use:** Pharmaceutical (Solution for Injection, used as opioid antagonist)

**Supplier:** **Teligent Canada Inc.**  
 5995 Avebury Road, Suite 804  
 Mississauga, Ontario L5R 3P9  
 1-800-656-0793

**Manufacturer:** **Teligent OÜ**  
 Akadeemia tee 21/5, Tallinn, Estonia

**Emergency Phone Number:**  
**Chemical Emergency Response Unit (Canada):** 1-613-946-5690  
**Poison Control Center (US):** 1-800-222-1222

**SECTION 2: HAZARD IDENTIFICATION**

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This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous.

**Classification of the Substance or Mixture**

**GHS – Classification:** Not classified as hazardous substance or mixture.

**Label Elements**

**Signal Word:** Not a hazardous substance or mixture  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

**SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS**

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Ingredients	CAS Number	Quantity	Acute toxicity: LD50 Oral, Rat
Naloxone Hydrochloride Dihydrate	51481-60-8	0.4 mg/mL	1250 mg/kg
Sodium Chloride	7647-14-5	9 mg/mL	3550 mg/kg
Hydrochloric Acid	7647-01-0	For pH adjustment	No data available
Water for Injection	7732-18-5	-	Not applicable

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**SECTION 4: FIRST AID MEASURES**

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- After Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- After Skin Contact:** Remove clothing and wash affected skin with plenty of soap and water. If irritation occurs or persists, get medical attention.
- After Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
- After Ingestion:** Never give anything by mouth to an unconscious person. Rinse mouth with water.

**SECTION 5: FIRE FIGHTING MEASURES**

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- Conditions of Flammability:** Not Flammable or Combustible
- Fire Fighting Instructions:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Explosion Hazards:** Not applicable.
- Extinguishing Media:** Use extinguishing media appropriate to surrounding fire conditions, such as water spray, dry chemical, alcohol-resistant foam, carbon dioxide.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**SECTION 7: HANDLING AND STORAGE**

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**Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

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**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store at room temperature between 15 and 30°C. Protect from light. Protect from freezing. For details information refer to the product packaging.

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

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**Control parameters**

No data available

**Personal Protection Equipment**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Eye Protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin Protection:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

**Hand Protection:** Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Respiratory Protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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<b>Physical State:</b>	Liquid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Not applicable
<b>Odour threshold:</b>	No data available
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture
<b>Specific Gravity:</b>	1.0047 g/mL
<b>pH:</b>	3.0 – 6.5
<b>Boiling Point:</b>	Mixture
<b>Freezing Point:</b>	Mixture
<b>Solubility in Water:</b>	Soluble

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**Flash Point:** No data available  
**Vapor Density:** No data available  
**Vapor Pressure:** No data available  
**Evaporation Rate:** No data available  
**Partition Coefficient:** No data available  
**Flammability:** No data available  
**Auto-ignition Temperature:** No data available  
**Decomposition Temperature:** No data available  
**Viscosity:** No data available

**SECTION 10: STABILITY AND REACTIVITY**

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**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions:** No data available  
**Conditions to Avoid:** Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing.  
**Incompatibility:** No data available  
**Hazardous Decomposition Products:** No data available

**SECTION 11: TOXIOLOGICAL INFORMATION**

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**Acute toxicity (Species, Root, Endpoint, Dose)**

<b>Product</b>			
Rat	Subcutaneous	MNTD*	50 mg/kg
Rat	Subcutaneous	LD50	520 mg/kg
<b>Naloxone Hydrochloride Dihydrate</b>			
Rat	Oral	LD50	1250 mg/kg
<b>Sodium Chloride</b>			
Rat	Oral	LD50	3550 mg/kg
Rabbit	Dermal	LD50	> 10000 mg/kg
Rat	Inhalation	LC50 – 1hr	> 42000 mg/m <sup>3</sup>

\*MNTD = maximum non-toxic dose

**Repeated dose toxicity**

No cumulative effects evident in rats, monkeys and dogs

**Other information on acute toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/eye irritation**

No data available

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**Respiratory or skin sensitization**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

None of the components of this formulation are listed as a carcinogen by IARC, ACGIH or OSHA.

**Reproductive toxicity and teratogenicity**

No effects evident in mice and rats at up to 1000 times the usual human dosage.

**SECTION 12: ECOLOGICAL INFORMATION**

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**Toxicity****Naloxone Hydrochloride Dihydrate**

No data available

**Sodium Hydroxide**

Toxicity to fish

LC50 - *Gambusia affinis* (Mosquito fish) - 125 mg/l - 96 hLC50 - *Oncorhynchus mykiss* (rainbow trout) - 45.4 mg/l - 96 h**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13: DISPOSAL CONSIDERATIONS**

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**Waste Disposal:** Dispose of in accordance with all applicable federal, state and local regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases.

**Packaging:** Dispose of in accordance with all applicable federal, state and local regulations. Handle packaging in the same way as the product itself.

**SECTION 14: TRANSPORTATION INFORMATION**

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Not regulated for transport under USDOT (transportation by land), IATA (transportation by air) or IMDG (transportation by sea) regulations.

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**SECTION 15: REGULATORY INFORMATION**

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The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

**SECTION 16: OTHER INFORMATION**

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The information contained in this Safety Data Sheet has been compiled from information believed to be accurate. While we believe that the data presented here is factual, Teligent Canada Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

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