

SAFETY DATA SHEET
Naloxone Hydrochloride Injection USP

1. Product and Company Information

Product Identifier: **Naloxone Hydrochloride Injection USP 0.4mg/mL**

Synonyms: None

National Drug Code: 70069-071-01

Recommended Use: Intravenous, Intramuscular or subcutaneous use

Company: Somerset Therapeutics LLC
 Hollywood, FL 33024

Contact Telephone: 1800-417-9175

E-Mail:

Emergency Phone Number: 1800-417-9175

2. Hazardous(s) Identification

Physical Hazards: None

Health Hazards: None

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: None

Supplementary Information: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

3. Composition and Information on Ingredients

Component	CAS
Naloxone Hydrochloride	51481-60-8
Sodium Chloride	7647-14-5
Hydrochloric Acid	7647-01-0
Water	7732-18-5

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for work place safety.

4. First Aid Measures

Eyes: Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek medical attention.

Skin: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Swallowed: DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. Seek medical attention.

Symptoms and effects of exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

5. Fire-Fighting Measures

Extinguishing Media:	Use carbon dioxide, dry chemical or water spray.
Hazardous Combustion Products:	No restrictions- As for primary cause of fire.
Fire Fighting Procedures:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Non-combustible. Not considered a significant fire risk. Where possible, contain and collect fire-fighting water for later disposal

6. Accidental Release Measures

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

Measures for cleaning and collecting: contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures of environmental protections: Place waste in an appropriate labelled, sealed container for disposal. Care should be taken to avoid environmental release.

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.

7. Handling and Storage:

General Handling: Avoid breathing vapour or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material

to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage

Conditions: Store as directed by product packaging.

20°C – 25°C (68°F – 77°F).

Protect from light by retaining in carton until ready for use. Discard unused portion

8. Exposure Controls / Personal Protection

Engineering controls:

None under normal operating conditions.

Environmental Exposure controls:

Refer to specific member state legislation for requirements under community environmental legislation.

Personal protective Equipment:

For good infection control, gloves should be worn when administering an injection.

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Physical state	Liquid
Molecular formula	Mixture
Color	Clear colourless
Molecular weight	Mixture

10. Stability and Reactivity

Stability: Stable at normal conditions

Conditions to Avoid: Not determined

11. Toxicological Information

Accidental Injection: May cause allergic reactions, nausea, palpitations, and increased blood pressure. Severe allergic reactions will usually occur within the first few hours of exposure. The sooner the onset of an allergic reaction, the more severe the reaction.

12. Ecological Information

Environmental overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. Disposal Conditions

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member state specific and Community specific provisions must be considered, considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and 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. This may include destructive techniques for waste and waste water.

14. Transportation Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

16. Other Information

Legend: NE- Not Established

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Revision Number: 01

Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.