



SAFETY DATA SHEET
PILOCARPINE HCL OPHTHALMIC SOLUTION, USP

1. Product and Company Information

Product Identifier: Pilocarpine HCL ophthalmic solution, USP
Synonyms: None
National Drug Code: 70069- 181-01 (15 mL-1%),
70069- 191-01 (15 mL-2%),
70069- 201-01 (15 mL-4%),
Recommended Use: Ophthalmic solution
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

Chemical Name	CAS Number
Pilocarpine hydrochloride	92-13-7
Benzalkonium chloride	8001-54-5
Sodium chloride USP	7440-23-5
Sodium citrate Dihydrate USP	6132-04-3
Boric acid NF	10043-35-3
Sodium hydroxide NF	1310-73-2
Hydrochloric acid	7647-01-0
Hypromellose USP	9004-65-3
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret.

4. First Aid Measures

- Eye Contact** If irritation occurs, immediately flush eyes with copious amounts of water. In the event of any adverse effects, obtain appropriate medical attention.
- Skin Contact:** If irritation occurs, immediately flush skin with copious amounts of water. In the event of any adverse effects, obtain appropriate medical attention.
- Inhalation:** Remove to fresh air. If not breathing, perform artificial respiration. If breathing is difficult, give oxygen. Obtain appropriate medical attention.
- Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves

5. Fire-Fighting Measures

- Extinguishing Media:** Water spray, carbon dioxide, dry chemical powder or ABC type.
- Hazardous Combustion Products:** Not determined.
- Fire Fighting Procedures:** Firefighters are recommended to wear self-contained breathing apparatus and full protective equipment. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.
- Fire / Explosion Hazards:** Not determined.

6. Accidental Release Measures

- Health and Safety Precautions:** Wear protective clothing, nitrile gloves and equipment consistent with the degree of hazard.
- Measures for Cleaning / Collecting:** Collect and place it in a suitable, properly labelled container for recovery or disposal.
- Measures for Environmental Protections:** For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and Storage:

- Handling:** Store in a tight container as defined in the united states pharmacopeia. This material should be handled and stored per label and other instructions to ensure product integrity.
- Storage:** Store the product 15 to 25°C (59 to 77°F).

8. Exposure Controls / Personal Protection

Exposure Limits None necessary for normal product handling

Hands: Not determined

Eyes: Safety glasses/goggles

Respiratory protection: NIOSH/MSHA-APPROVED

Skin protection Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Appearance:	Liquid
pH:	3.5-5.5
Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available
Vapour Pressure (kPa):	No data available
Vapour Density (g/ml):	No data available
Specific Gravity:	Comparable to water
Viscosity:	No data available
Flammability:	Not flammable
Flash Point (Liquid) (°C):	Not flammable
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. Stability and Reactivity

Reactivity:	Stable
Chemical Stability:	Stable under recommended storage conditions.
Incompatible Materials:	None known
Hazardous Decomposition Products	Emits toxic fumes including nox and sox.
Hazardous Polymerization	Will not occur

11. Toxicological Information

TOXICITY:

The oral-rat LD50 for pilocarpine is:

200 MG/KG. Pilocarpine is classified a "toxic" by OSHA.

This chemical mixture is classified as "toxic", based on the reported oral LD50 in rats.

Pilocarpine is the only pharmacologically active ingredient.

CARCINOGENICITY:

No components of this chemical mixture are classified as carcinogenic by OSHA, the NTP or the IARC.

Acute effects:

Inhalation:	Is not an inhalation hazard.
Ingestion:	May cause eye redness, miosis, sweating, salivation
Skin Contact:	Minimal or mild irritation may occur up on exposure
Eye Contact:	May cause eye irritation, conjunctival redness

12. Ecological Information

Eco toxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bio accumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Conditions

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transportation Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name: CONSUMER COMMODITY

IATA UN/ID No: 8000

IATA Hazard Class: 9

IATA Packaging Group: 910

IATA Label: MISCELLANEOUS

IMDG - Not Regulated

IMDG Proper shipping Name: N/A

IMDG UN/ID No: N/A

IMDG Hazard Class: N/A

IMDG Flash Point: N/A

IMDG Label: N/A
DOT - Not Regulated
DOT Proper shipping Name: N/A
DOT UN/ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point: N/A
DOT Packing Group: N/A
DOT Label: N/A

15. Regulatory Information

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):**

Not applicable

FDA Designations:

Prescription only medication.

NDC No. 70069- 181-01 (15 mL-1%),
70069- 191-01 (15 mL-2%),
70069- 201-01 (15 mL-4%),

Other Information

NFPA Rating:

Health: 1
Flammability: 1
Reactivity: 0

Revision Date: 10/05/2019

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.