

SAFETY DATA SHEET

Tropicamide ophthalmic solution USP 1%

1. Product and Company Information

Product Identifier: Tropicamide Ophthalmic Solution USP 1%
Synonyms: None
National Drug Code: 70069-121-01 (1%-15ml)
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

Component	CAS	Percentage
Tropicamide USP	1508-75-4	1.00%
Benzalkonium chloride NF	8001-54-5	0.01%
Edetate disodium USP dihydrate	6381-92-6	0.01%
Sodium chloride USP	7647-14-5	0.69%
Sodium Hydroxide NF	1310-73-2	Qs to adjust pH
Hydrochloric acid NF	7647-01-0	Qs to adjust pH
Water for injection IH	NA	Qs

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

4. First Aid Measures

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes.

Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Immediately administer slurry of activated charcoal. The use of an emetic

drug and/or gastric lavage is advisable. Wash out mouth and give plenty of water and bland fluids. Do not give anything to an unconscious person. Seek professional assistance.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact a physician immediately.

Note to Physicians:

- Tropicamide may interfere with the antiglaucoma and miotic actions of ophthalmic Cholinesterase inhibitors.
 - Tropicamide is contraindicated in cases of primary and narrow angle glaucoma or Anatomical narrow angles.
 - It is not known whether this drug is excreted in the milk of nursing mothers, so caution.
- Should be exercised when prescribing tropicamide.
- CNS disturbances are more likely in young, premature, or small infant.

5. Fire-Fighting Measures

Extinguishing Media:

Flash point: Not Established Method: Not Established

Hazardous Combustion Products:

Toxic fumes.

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

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

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 8 to 27°C (46 to 80°F).

8. Exposure Controls / Personal Protection

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain dust and vapour levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical materials and use of current Material Safety Data Sheets.

Eye Protection: Recommend goggles or chemical safety glasses

Skin Protection: Thick impermeable gloves and protective clothing

Respiratory Protection: NIOSH approved respirator, with organic vapour, acid gas and HEPA filter is recommended for handling raw materials. No respiratory protection is required in the clinical or home environment.

Warning: Do not use air purifying respirators in oxygen depleted environments.

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system and/or according to Federal, State and Local regulations.

9. Physical and Chemical Properties

Appearance:	Liquid
pH:	4.0-5.8
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

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold

Incompatibility: This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Toxic fumes

Hazardous Polymerization: Should not occur

11. Toxicological Information

Summary of Risks: Toxicological information refers to the raw materials of the product.

Concentrations and toxicological effects are substantially reduced in the product. For more

Detailed information see MSDS on each chemical material.

Tropicamide

May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can cause temporary light sensitivity and an increase in intraocular pressure. Over dosage (systemic toxicity) of anticholinergics are manifested by dryness of the mouth, nose, throat and bronchi, blurred vision, photophobia, a rapid and irregular pulse, mental aberration (hallucinations) unusual drowsiness, hyperpyrexia, and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression hyperpyrexia, and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression.

12. Ecological Information

Avoid release in to environment

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

Transportation Data: Not classified as hazardous by DOT regulations.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act

(TSCA):

Not applicable

FDA Designations:

Prescription only medication.

NDC No. 70069- 121-01

16. Other Information

Legend: NE- Not Established

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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.