

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Tropicamide Ophthalmic Solution, USP

Synonyms: Benzeneacetamide, N-ethyl-alpha-(hydroxymethyl)-N-(4-pyridinylmethyl)-, (+/-)-

National Drug Code (NDC): 17478-101-12
17478-102-12
17478-102-20

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

| Chemical Name | CAS Number | Synonyms | Chemical Formula | Molecular Weight | Percentage |
|---------------|------------|--|---|------------------|------------|
| Tropicamide | 1508-75-4 | Benzeneacetamide, N-ethyl-alpha-(hydroxymethyl)-N-(4-pyridinylmethyl)-, (+/-)- | C ₁₇ H ₂₀ N ₂ O ₂ | 284.36 | 0.5% or 1% |

*The formula also contains Benzalkonium Chloride, 0.01% as a preservative; Edetate Disodium, Sodium Chloride, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH between 4.0 – 8.8 and Water for Injection.

4. First Aid Measures

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.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Not determined.

Medical Conditions Aggravated by Exposure: Hypersensitivity to any of the components of the product. Animal reproduction studies have not been performed with Tropicamide. It is also not known whether Tropicamide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Tropicamide should be given to pregnant woman only if clearly needed.

Notes to Physician: 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.

SDS: Tropicamide Ophthalmic Solution, USP

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 infants.

5. Firefighting Measures

Suitable Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Toxic fumes.

Other Specific Hazards: Not determined.

**Special Protective Equipment/
Precautions for Firefighters:** Use water spray to keep fire-exposed containers cool. Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: 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.

Environmental Precautions: Product administered to patients presents a negligible impact on the environment.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product and use caution to prevent puncturing containers. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store product upright in original containers with the cap tightly closed at controlled room temperature between 15°C – 30°C (59°F – 86°F). Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

Occupational Exposure Guidelines:

| Common or Chemical Name | Employee Exposure Limits |
|-------------------------|--------------------------|
| Tropicamide | Not established. |

Engineering Controls:

In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain dust and vapor 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 Safety Data Sheets.

Respiratory Protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). WARNING: Do not use air purifying respirators in oxygen depleted environments.

Eyes Protection:

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

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

Contaminated Equipment:

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

9. Physical and Chemical Properties

| | |
|---|----------------------------|
| Physical State/Color: | Clear, colorless solution. |
| Odor: | No data available. |
| Odor Threshold: | No data available. |
| pH: | 4.0 – 5.8. |
| Melting Point: | No data available. |
| Freezing Point: | No data available. |
| Boiling Point: | No data available. |
| Flash Point: | No data available. |
| Evaporation Rate: | No data available. |
| Flammability (solid, gas): | No data available. |
| Flammability Limit - Lower: | No data available. |
| Flammability Limit - Upper: | No data available. |
| Vapor Pressure: | No data available. |
| Vapor Density: | No data available. |
| Relative Density: | No data available. |
| Solubility(ies): | Soluble in water. |
| Partition Coefficient (n-octanol/water): | No data available. |
| Auto-Ignition Temperature: | No data available. |
| Decomposition Temperature: | No data available. |
| Viscosity: | ~Aqueous. |
| Specific Gravity: | 1.007 g/mL |

10. Stability and Reactivity

| | |
|---|---|
| Reactivity: | No data available. |
| Chemical Stability: | Stable under recommended storage conditions. |
| Possibility of Hazardous Reactions: | No data available. |
| Conditions to Avoid (e.g., static discharge, shock, or vibration): | Extreme heat or cold. |
| Incompatible Materials: | 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**Information on the Likely Routes of Exposure:**

| | |
|---------------------|--|
| Tropicamide: | May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can cause temporary light sensitivity and an increase in intraocular pressure. Overdosage (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) |
|---------------------|--|

SDS: Tropicamide Ophthalmic Solution, USP

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.

| | |
|--|--|
| Inhalation: | May cause irritation and hypersensitivity in some individuals. |
| Ingestion: | May cause irritation, vomiting, diarrhea and hypersensitivity in some individuals. Ingestion of tropicamide may induce systemic toxicity effects. |
| Skin Contact: | May cause irritation and hypersensitivity in some individuals. Toxic systemic effects may be induced by skin contact. |
| Eye Contact: | May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can cause temporary light sensitivity and increased intraocular pressure. Over dosage (systemic toxicity) is manifested by headache, blurred vision, a rapid and irregular pulse, psychotic reactions, unusual drowsiness and dry mouth. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression. The main symptoms are drowsiness leading to coma. Once the drug is withdrawn, the mechanism of over dosage is self-limiting. |
| Symptoms Related to the Physical, Chemical and Toxicological Characteristics: | See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated. |
| Delayed and Immediate Effects of Exposure: | No data available. |
| Acute Toxicity – Oral: | No data available. |
| Acute Toxicity – Dermal: | No data available. |
| Acute Toxicity – Inhalation: | No data available. |
| Corrosivity: | No data available. |
| Dermal Irritation: | No data available. |
| Eye Irritation: | No data available. |
| Sensitization: | No data available. |
| Toxicokinetics/Metabolism: | No data available. |
| Target Organ Effects: | Eyes, central nervous system, respiratory and digestive tract. |
| Reproductive Effects: | No data available. |
| Carcinogenicity: | No data available. |

SDS: Tropicamide Ophthalmic Solution, USP

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.
Aspiration Hazard: No data available.

Chronic Effects: May cause irritation: May cause hypersensitivity. Severe reactions are manifested by hypotension with progressive respiratory depression.

12. Ecological Information

Ecotoxicity

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

13. Disposal Considerations

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

14. Transport Information

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SDS: Tropicamide Ophthalmic Solution, USP

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

Revision Date: 05/15/2015

Revision Number: 1

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.