

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 074

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Tropicamide Ophthalmic Solution USP, 1.0%
Generic Name: Same
NDC No. 24208-585-59 (2 ml, box of 12)
24208-585-64 (15 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Mydriatic (Opens pupil)

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

| Description | CAS # | TLV (mg/m ³) | PEL(mg/m ³) | % Content |
|----------------|------------|--------------------------|-------------------------|-----------|
| Tropicamide | 1508-75-4 | NE | NE | 1.0 |
| Boric Acid | 10043-35-3 | NE | NE | ≥1 |
| Purified Water | 7732-18-5 | NE | NE | ≥1 |

Ingredients <1% - Edetate Disodium, Hydrochloric Acid, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless and odorless, aqueous solution. Do not engage in hazardous activity while under the influence. May cause temporary light sensitivity. Avoid mouth and skin contact. Toxic by ingestion and skin contact.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause temporary light sensitivity and increased intraocular pressure. Overdosage (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 Once the drug is withdrawn, the mechanism of overdosage is self limiting.

Skin: May cause irritation and hypersensitivity in some individuals. Toxic systemic effects may be induced by skin contact.

Ingestion: May cause irritation, vomiting, diarrhea and hypersensitivity in some individuals. Ingestion of tropicamide can induce systemic toxicity effects.

Inhalation: May cause irritation and hypersensitivity in some individuals.

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

Target Organs: Eyes, central nervous system, respiratory and digestive tract.

Medical Conditions Aggravated by Long Term 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. Tropicamide is contraindicated in cases of primary and narrow angle glaucoma or anatomical narrow angles.

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 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 infants.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water fog and foam for surrounding materials. Water spray will froth if sprayed into the burning material.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

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: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-30⁰ C (59⁰- 86⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the 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 material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

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. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor: Clear, colorless, odorless aqueous solution.

| | | | |
|-------------------|-----|-------------------|----|
| Boiling Point: | NE | Evaporation Rate: | NE |
| Specific Gravity: | 1.0 | Vapor Density: | NE |

| | | | |
|-------------------|----------|-----------------------------|----|
| Vapor Pressure: | NE | Viscosity: | NE |
| Water Solubility: | Complete | Percent Volatile by Volume: | <1 |

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. TOXICOLOGY 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 chemical material.

CAS#

1508-75-8 **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) unusual drowsiness, hyperpyrexia, and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression.

10043-35-3 **Boric Acid**

Inhalation can cause coughing and chest discomfort. Prolonged skin contact can cause burns and sensitization. Ingestion can cause nausea and vomiting. Swallowing large quantities may be fatal and chronic exposure can cause central nervous system stimulation and skin redness or rash. Oral-rat LD₅₀ 2660 mg/kg, Inhalation-rat LC₅₀ >16 mg/L.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible

impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-585-59 (2 ml, box of 12)
NDC No. 24208-585-64 (15 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

> - Greater Than

< - Less Than