

MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 1%

Manufacturer: Akorn Incorporated
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Section 1 - IDENTIFICATION

TRADE NAME: Tropicacyl® (Tropicamide Ophthalmic Solution USP, 1%)
Description: Anticholinergic, Mydriatic (sterile)

<u>Composition</u>	<u>CAS#</u>	<u>TLV(mg/m³)</u>	<u>PEL(mg/m³)</u>	<u>%Content</u>
Tropicamide, USP	1508-75-4	NE	NE	1.0
Sodium Chloride, USP	7647-14-5	None	None	0.6
Edetate Disodium, USP	139-33-3	None	None	0.01
Benzalkonium Chloride, NF	8001-54-5	None	None	0.01
Water for Injection, USP	7732-18-5	None	None	Q.S. Sodium
Hydroxide, NF and Hydrochloric Acid, NF added for pH adjustment				

Common name of active ingredient: Tropicamide
Chemical Formula: C₁₇H₂₀N₂O₂
Molecular Weight: 284.36 g/mole
Legal Category: Prescription only

Section 2 - HAZARDOUS IDENTIFICATION

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can 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 Once the drug is withdrawn, the mechanism of overdosage is self-limiting.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 may 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



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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.

Section 3 - 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 infants.

Section 4 - FIRE FIGHTING MEASURES

- Flammable Properties:** Flash point: Not Established Method: Not Established
- Hazardous Products:** Toxic fumes
- Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials
- Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

Section 5 - 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.

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Section 6 - 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 between 15° to 30°C (59° - 86°F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Section 7 - EXPOSURE CONTROL / PERSONAL PROTECTION

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 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 vapor, 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.

Section 8 - CHEMICAL & PHYSICAL PROPERTIES

Appearance: Clear, colorless solution.

Boiling Point: Not Established

Specific Gravity: 1.008 g/mL

Vapor Pressure: Not Established

Water Solubility: Complete

Latex Free: Yes

Evaporation Rate: NE

Vapor Density: NE

Viscosity: ~aqueous

pH: 4.0 to 5.8

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Section 9 - 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

Section 10 - 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 each chemical material.

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 hyperpyrexia, and loss of neuromuscular coordination. Severe reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression.

Section 11 - ECOLOGICAL INFORMATION

Chemical Fate Information:	Product administered to patients presents a negligible impact on the environment.
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Section 12 - 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		

Section 13 - TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.



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Section 14 - 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. 24208-590-64 (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

Section 15 - OTHER INFORMATION

Legend: NE- Not Established

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