

SAFETY DATA SHEETS

This SDS packet was issued with item:

078859765

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078859773

**MSDS: PROPARACAINE HCl
OPHTHALMIC SOLUTION
USP, 0.5%**

Material Safety Data Sheet

Manufacturer: Akorn Inc. Telephone: (217) 428-1100
150 S. Wyckles Road
Decatur, IL 62522

Section 1- IDENTIFICATION

TRADE NAME: Proparacaine Hydrochloride Ophthalmic Solution, 0.5% USP

Description: Local anesthetic

Composition	CAS#	TLV(mg/m ³)	PEL(mg/m ³)	%Content
Proparacaine HCl	5875-06-9	NE	NE	0.5
Glycerin	56-81-5	10	NE	≥1
Purified Water	NA	NE	NE	≥1

Ingredients <1%

Hydrochloric Acid, Benzalkonium Chloride

Common name of active ingredients: Proparacaine HCl

Chemical Formula (s): C₁₆H₂₆N₂O₃·HCl

Prescription only medicine filled inside plastic bottle and overpacked inside a cardboard carton.

NE= Not established

Section 2- HAZARDOUS INGREDIENTS

EMERGENCY OVERVIEW

Plastic bottle in cardboard box. Clear, colorless aqueous solution. Avoid ingestion.

Principal Hazardous Ingredients: Proparacaine HCl

% Threshold Limit Value: NE

Carcinogenicity:

NTP- No

IARC- No

OSHA-No

NE= Not established

**MSDS: PROPARACAINE HCl
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Section 3- PHYSICAL AND CHEMICAL CHARACTERISTICS

Boiling Point (C°): NE
Vapor Pressure (mm Hg): NE
Solubility in Water: Soluble
Specific Gravity: 1.0
Percent Volatile: <1
Evaporation Rate: NE
Reactivity in Water: None
Appearance and Odor: Clear, colorless, aqueous solution.
NE= Not established

Vapor Density: NE
Viscosity: NE

Section 4- FIRE AND EXPLOSION HAZARD DATA

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

Auto Ignition Temperature: NE **Method:** NE

Special Firefighting Procedures: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

Hazardous Products: Emits toxic fumes.

Stability: Stable X Unstable

CONDITIONS TO AVOID

Incompatibility: This product has the same incompatibilities as water e.g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

Conditions to Avoid: Extreme heat or cold.

Section 5- REACTIVITY DATA

NA

Section 6- HEALTH HAZARDS

Threshold Limit Value: NE

**MSDS: PROPARACAINE HCl
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Signs and Symptoms of Exposure:

1. **Acute Overexposure:** Possible eye and/or skin irritation
2. **Chronic Overexposure:**
 - *Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently creating a "vicious circle". Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur.
 - *May cause hypersensitivity in some individuals.

Medical Conditions Aggravated by Long Term Exposure

*Individuals sensitive to ester-type local anesthetics (e.g. benzocaine, butacaine, butamben, chlorprocaine, tetracaine, propoxycaine) or to PABA may be hypersensitive to proparacaine.

*It is not known if proparacaine can cause fetal harm or impair reproductive capacity. This medication should only be given to pregnant women if clearly needed.

*It is not known if proparacaine is excreted in human milk, so caution should be exercised when administering this medication.

Chemical Listed as Carcinogen or Potential Carcinogen:

National Toxicology Program: Yes _____ No x

I.A.R.C Monographs: Yes _____ No x

OSHA: Yes _____ No x

OSHA Permissible Exposure Limit: NE

ACGIH Threshold Limit Value: NE

Other Exposure Limit Used: NE

NE= Not established

Emergency and First Aid Procedures:

1. **Inhalation:** May cause irritation and hypersensitivity in some individuals.
 - a. **First Aid Inhalation:**
Remove person to fresh air, and if breathing stops, use artificial respiration.
Contact physician.
2. **Eyes:** May cause temporary stinging, burning, and conjunctival redness. In the unlikely event irritation occurs it is most likely several hours after installation. After installation, do not rub eyes. The surface of the eye is sensitive and can be scratched without feeling it. May cause hypersensitivity. Although exceedingly rare, ophthalmic applications of proparacaine can cause central nervous system stimulation followed by depression. A rare, severe, immediate allergic corneal reaction has been reported, characterized by acute diffuse filament formation and/or sloughing of large areas of dead skin, swelling and inflammation of the iris.

**MSDS: PROPARACAINE HCl
OPHTHALMIC SOLUTION
USP, 0.5%**

- a. **First Aid Eyes:**
Rinse immediately with copious amounts of water for at least 20 minutes.
Contact a physician.
- 3. **Skin:** May cause irritation and hypersensitivity in some individuals. Allergic contact dermatitis with drying and fissuring of the fingertips can occur.
 - a. **First Aid Skin:**
Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.
- 4. **Ingestion:** May cause irritation and hypersensitivity. Moderately toxic by ingestion; however, very large quantities may induce yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, convulsions, respiratory failure, cardiac arrhythmias or arrest and coma.
 - a. **First Aid Ingestion:**
Wash out mouth. Give plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

Note to physician:
None

Section 7- PROTECTION INFORMATION

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator 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.

Ventilation: Recommended

Mechanical/ 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 materials and use current Material Safety Data Sheets.

Skin Protection: Use thick impermeable rubber gloves and protective clothing.

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

**MSDS: PROPARACAINE HCl
OPHTHALMIC SOLUTION
USP, 0.5%**

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.

Other: None

Section 8- SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Precautions to be taken in handling and storage: 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 15°-30° C (59°- 86°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Steps to be taken in case material is released or spilled: 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.

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

Section 9- TOXICOLOGY INFORMATION

Summary of risks: Toxicology information refers to raw material of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

5875-06-9

Proparacaine HCl

May cause irritation to eyes, skin, and respiratory tracts. Can cause hypersensitivity (anaphylactic) in some individuals. Effects include excitation of the central nervous system (yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, convulsions), respiratory failure, cardiac arrhythmias, cardiac arrest and coma. Should be avoided by individuals sensitive to other ester-type local anesthetics (e.g. benzocaine, butacaine, butamben, chlorocaine, tetracaine, propoxycaine) or PABA. Subcutaneous mouse LD₅₀ 64 mg/kg, Intravenous mouse LD₅₀: 3371 micrograms/kg.

**MSDS: PROPARACAINE HCl
OPHTHALMIC SOLUTION
USP, 0.5%**

56-81-5

Glycerin

May cause irritation to eyes, and skin. Repeated or prolonged exposure to the eyes may cause dermatitis and exposure to the eyes may cause conjunctivitis. Inhalation is not likely due to low evaporation rate, but fumes may cause irritation and defatting of the tissues. Ingestion may cause headache, restlessness, insomnia, dizziness, vomiting, diarrhea, and fever. Large doses may cause hemolysis, hemoglobinuria, hyperglycemia, glycosuria, renal failure, convulsions, narcosis, and paralysis. Oral rat LD₅₀ 12,600 mg/kg. Decomposition of raw material releases corrosive fumes of acrolein. Avoid open flames and extreme heat. Incompatibilities include strong acids, strong oxidizers, metal oxides and metal hydrides.

Section 10- ECOLOGICAL INFORMATION

Chemical fate information: Product administered to patients presents a negligible impact on the environment.

Other Precautions: None

The information given herein is in good faith and to the best of our knowledge but no warranty expressed or implied is made

Prepared By

John A. [Signature]

Date: 03-30-2005



MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 0.5%

Manufacturer: Akorn Incorporated
150 S. Wyckles Road
Decatur, IL 62522
Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

TRADE NAME: Tropicacyl® (Tropicamide Ophthalmic Solution USP, 0.5%)
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	0.5
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



MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 0.5%

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.



MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 0.5%

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

Section 8 - CHEMICAL & PHYSICAL PROPERTIES

Appearance: Clear, colorless solution

Boiling Point: Not Established

Specific Gravity: 1.007 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



MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 0.5%

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	



MSDS: Tropicacyl®
Tropicamide Ophthalmic Solution USP, 0.5%

Section 13 - TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

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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SDS: Proparacaine Hydrochloride Ophthalmic Solution,
USP 0.5%

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Proparacaine Hydrochloride Ophthalmic Solution,
USP 0.5%

Synonyms: Proxymetacaine hydrochloride

National Drug Code (NDC): 17478-263-12

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: None.

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
Proparacaine Hydrochloride	5875-06-9	Proxymetacaine hydrochloride	C ₁₆ H ₂₆ O ₃ •HCl	330.86	0.5%

*The formula also contains Benzalkonium Chloride, 0.01% as preservative. Glycerin as stabilizer, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH between 3.5 – 6.0 and Water for Injection.



SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

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:**

Individuals sensitive to ester-type local anesthetics (e.g. butacaine, butamben, chloroprocaine, tetracaine, propoxycaine) or to PABA may be hypersensitive to proparacaine. It is not known if proparacaine can cause fetal harm or impair reproductive capacity. This medication should only be given to pregnant women if clearly needed. It is not known if proparacaine is excreted in human milk, so caution should be exercised when administering this medication.

Notes to Physician:

Additional details are available on the package insert or in the Physicians' Desk Reference.



SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

5. Firefighting Measures

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

Caution: Carbon dioxide will displace air in confined spaces and may cause oxygen deficient atmosphere.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Not determined.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

Fire Fighting Instructions: Use water spray to keep fire exposed containers cool. Do not spray water into the burning material.

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. Absorb liquid with clay absorbent, absorbent pads or paper towels. Shovel, scoop up, sweep or containerize spilled material.

Environmental Precautions: It is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

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

7. Handling and Storage

Precautions for Safe Handling: 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:** If solution shows more than a faint yellow color, it should not be used. Refrigerate between 2°C – 8°C (36°F – 46°F). Keep bottle tightly closed. Store in carton until is empty to protect from light. Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Proparacaine Hydrochloride	Not established.
Benzalkonium Chloride	Not established.

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 TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment.

Respiratory Protection:

No respiratory protection is required in the clinical or home environment. 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:

Not required for the normal use of this product. 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 contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless aqueous solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	No data available.
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):	Nonflammable, noncombustible.
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):	Freely soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Volatile:	<1.
Specific Gravity:	1.0.

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 the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May cause irritation and hypersensitivity.
Ingestion:	May cause irritation and hypersensitivity. Moderately toxic by ingestion; However, very large quantities may induce yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, convulsions, respiratory failure, cardiac arrhythmias or arrest and coma.

SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

Skin Contact:	May cause irritation and hypersensitivity in some individuals. Allergic contact dermatitis with drying and fissuring of the fingertips can occur.
Eye Contact:	May cause temporary stinging, burning, and conjunctival redness. In the unlikely event irritation occurs it is most likely several hours after installation. After installation do not rub eye. The surface of the eye is sensitive and can be scratched without feeling it. May cause hypersensitivity. Although exceedingly rare, ophthalmic applications of proparacaine can cause central nervous system stimulation followed by depression. A rare, severe, immediate allergic corneal reaction has been reported, characterized by acute diffuse filament formation and/or sloughing of large areas of dead skin, swelling and inflammation of the iris.
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:	

Compound	Species	Route	Type	Dose
Glycerin	Rat	Oral	LD ₅₀	12,600 mg/kg
Proparacaine HCl	Mouse	Subcutaneous	LD ₅₀	64 mg/kg
Proparacaine HCl	Mouse	Intravenous	LD ₅₀	3,371 mg/kg

Proparacaine HCl:	May cause irritation to eyes, skin and respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals. Effects include excitation of the central nervous system (yawning, restlessness, dizziness, blurred vision, nausea, vomiting, muscle twitching, convulsions), respiratory failure, cardiac arrhythmias, cardiac arrest and coma. Should be avoided by individuals sensitive to other ester-type local anesthetics (e.g. benzocaine, butacaine, butamben, chlorocaine, tetracaine, propoxycaine) or PABA.
Glycerin:	May cause irritation to eyes and skin. Repeated or prolonged exposure may cause dermatitis and eye conjunctivitis. Inhalation is not likely due to low evaporation rate, but fumes may cause irritation and defatting of the tissues. Ingestion can cause headache, restlessness, insomnia, dizziness, vomiting, diarrhea and fever. Large doses can cause hemolysis, hemoglobinuria, hyperglycemia, glycosuria, renal failure, convulsions, narcosis and paralysis. Decomposition releases corrosive fumes of acrolein. Avoid open flame and extreme heat. Incompatibilities include strong acids, strong oxidizers, metal oxides and metal hydrides.



SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

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:	Central nervous system.
Reproductive Effects:	No data available.
Carcinogenicity:	Does not contain any carcinogens or potential carcinogens.
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:	Based on available data, the classification criteria are not met.
Chronic Effects:	Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently creating a “vicious circle”. Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur. May cause hypersensitivity in some individuals.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No applicable bioaccumulation is expected in the environment.
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.



SDS: Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

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

State Regulations

California Proposition 65:	Not listed.
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16. Other Information

Revision Date: 05/12/2015

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.



SDS: Tropicamide Ophthalmic Solution, USP

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.

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.

SDS: Tropicamide Ophthalmic Solution, USP

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)
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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

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