



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.

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.

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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.

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.

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.

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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.

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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.

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

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