

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%
<b>Synonyms:</b>	Proxymetacaine hydrochloride
<b>National Drug Code (NDC):</b>	17478-263-12
<b>Recommended Use:</b>	Pharmaceutical. Proparacaine Hydrochloride Ophthalmic Solution is indicated for topical anesthesia in ophthalmic practice.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classified.	
<b>Health Hazards:</b>	Skin Sensitization	Category 1B



<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H317 May cause an allergic skin reaction.	
<b>Precautionary Statement(s):</b>	P261 Avoid breathing vapor or spray. P264 Wash hands thoroughly after handling. P272 Contaminated work clothing should not be allowed out of workplace. P280 Wear protective gloves/ protective clothing/ eye protection and face protection. P302 IF ON SKIN: Wash with plenty of soap and water. + P352 P333 If skin irritation or rash occurs: Get medical attention. + P313	

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

P305 IF IN EYES: Rinse cautiously with water for  
 + several minutes. Remove contact lenses, if  
 P351 present and easy to do. Continue rinsing.  
 +  
 P338

P337 If eye irritation persists: Get medical attention.  
 +  
 P313

P501 Dispose of contents/ container in accordance  
 with local/ regional/ national/ international  
 regulations.

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Proparacaine Hydrochloride	Proxymetacaine hydrochloride	5875-06-9	C <sub>16</sub> H <sub>26</sub> N <sub>2</sub> O <sub>3</sub> •HCl	330.86	0.5%

The formula also contains the following inactive ingredients: Benzalkonium Chloride, 0.01%, Glycerin, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH between 3.5 to 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

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

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:**

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, and convulsions), respiratory failure, cardiac arrhythmias, cardiac arrest and coma.

**Medical Conditions Aggravated by Exposure:**

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

**Notes to Physician:**

Treat supportively and symptomatically.

### 5. FIREFIGHTING MEASURES

**Suitable Extinguishing Media:**

Use water, carbon dioxide, dry chemical or foam as necessary.

**Unsuitable Extinguishing Media:**

Not determined.

**Specific Hazards Arising from the Chemical**

**Hazardous Combustion Products:**

None.

**Other Specific Hazards:**

Closed containers may explode from the heat of fire.

**Special Protective Equipment and Precautions for Firefighters:**

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.

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

**Methods for Cleaning Up:** Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

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

**Specific End Use:** Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Proparacaine Hydrochloride	Not established	Not established

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Respiratory protection is normally not required during intended product use. 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).

**Eyes Protection:** Eye protection is normally not required during intended product use. 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:** Hand protection is normally not required during intended product use. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

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.

**General Hygiene Considerations:**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Clear, colorless aqueous solution.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	3.5 to 6.0.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	Nonflammable, noncombustible.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Freely soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Extreme heat or cold. Do not freeze. Protect from light and heat.
<b>Incompatible Materials:</b>	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

**Hazardous Decomposition Products:** No data available.

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

**Inhalation:** May cause irritation and hypersensitivity.

**Ingestion:** 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.

**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. 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Proparacaine Hydrochloride	Mouse	Subcutaneous	LD <sub>50</sub>	64 mg/kg
Proparacaine Hydrochloride	Mouse	Intravenous	LD <sub>50</sub>	3,371 mcg/kg

#### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available
No data available	No data available	No data available	No data available
No data available	No data available	No data available	No data available

<b>Aspiration Hazard:</b>	None anticipated from normal handling of this product.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	Based on clinical use, possible target organs include the nervous system.
<b>Reproductive Effects:</b>	Pregnancy Category C. Animal reproduction studies have not been conducted with Proparacaine Hydrochloride Ophthalmic Solution.
<b>Carcinogenicity:</b>	Long term studies in animals have not been performed to evaluate the carcinogenic potential.
<b>National Toxicology Program (NTP):</b>	Not considered to be a carcinogen.
<b>International Agency for Research on Cancer (IARC):</b>	Not considered to be a carcinogen.
<b>Occupational Safety and Health Administration (OSHA):</b>	Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No applicable bioaccumulation is expected in the environment.

# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

**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

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Proparacaine Hydrochloride	No

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable



# SAFETY DATA SHEET

## Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%

### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Proparacaine Hydrochloride	Not Listed	Not Listed	Not Listed

**California Proposition 65:**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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