

**MATERIAL SAFETY DATA SHEET**

Issued: 11/16/94	Prepared by: Gary Wong
Revised: 09/30/04	Manager EHS
Revision: 02	Core No. 047

**1. PRODUCT AND COMPANY INFORMATION**

**Product Name:** Proparacaine Hydrochloride Ophthalmic Solution USP, 0.5%  
**Generic Name:** Same  
**NDC No.** 24208-730-06 (15 ml)

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

**Drug Composition:** Local anesthetic

BAUSCH & LOMB INCORPORATED  
 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 <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	% Content
Proparacaine HCl	5875-06-9	NE	NE	0.5
Glycerin	56-81-5	10 (mist)	15 (Total mist) 5 (Respirable Fraction)	≥1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Hydrochloric acid, Benzalkonium Chloride

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

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

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#### POTENTIAL HEALTH HAZARDS

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

**Eye:** 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.

**Skin:** May cause irritation and hypersensitivity in some individuals. Allergic contact dermatitis with drying and fissuring of the fingertips can occur.

**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.

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

#### 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.

**Target Organs:** Central nervous system.

#### Medical Conditions Aggravated by Long Term 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.

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#### 4. FIRST AID MEASURES

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**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:** Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

**Note to Physicians:** Additional details are available on the package insert or in the Physicians Desk Reference.

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#### 5. FIRE FIGHTING MEASURES

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**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.

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#### 6. ACCIDENTAL RELEASE MEASURES

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**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 2<sup>0</sup>-8<sup>0</sup> C (36<sup>0</sup>- 46<sup>0</sup> 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 contaminated 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 aqueous solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Soluble	Percent Volatile by Volume:	<1

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## 10. STABILITY AND REACTIVITY

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**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:**

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY

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

CAS #

5875-06-9

### **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. Subcutaneous-mouse LD<sub>50</sub> 64mg/kg, Intravenous-mouse LD<sub>50</sub> 3371 micrograms/Kg.

56-81-5

### **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. Oral-rat LD<sub>50</sub> 12,600 mg/kg. 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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## 12. ECOLOGICAL INFORMATION

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

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## 13. DISPOAL INFORMATION

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**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

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## 14. TRANSPORTATION INFORMATION

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**Transportation Data:** Not classified as hazardous by DOT regulations.

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## 15. REGULATORY INFORMATION

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**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. 24208-730-06 (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

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## 16. OTHER INFORMATION

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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.

BAUSCH & LOMB INCORPORATED

MSDS: Proparacaine Hydrochloride Ophthalmic Solution USP, 0.5%

NE- Not Established

< - Less Than

> - Greater Than