

MATERIAL SAFETY DATA SHEET

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Revision: 02

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Core No. 091

1. PRODUCT AND COMPANY INFORMATION

Product Name: Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%
Generic Name: Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%
NDC No. 24208-920-64 (15ml)

Legal Category: Prescription only medicine, filled inside glass 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 ³)		PEL (mg/m ³)	% Content
Tetracaine HCL	136-47-0	NE	NE		0.5
Boric Acid	10043-35-3	NE	NE		≥1
Purified Water	7732-18-5	NE	NE		≥1

Ingredients <1% - Chlorobutanol, Potassium Chloride, Edetate Disodium.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Colorless, to slightly yellow, aqueous solution with camphor like odor.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause temporary stinging, burning, and conjunctival redness. After installation, the eye may be scratched without pain, so should not be rubbed. 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. May cause hypersensitivity.

Skin: May cause irritation and hypersensitivity in some individuals.

Ingestion: May cause irritation and hypersensitivity. Moderately toxic by ingestion; however, very large quantities may induce yawning, restlessness, dizziness, burred 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. benzocaine, butacaine, butamben, chloroprocaine, tetracaine, propoxycaine) or to PABA may be hypersensitive to tetracaine.
- It is not known if tetracaine 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 tetracaine is excreted in human milk, so caution should be exercised when administering this medication.

4. 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: 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.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Toxic fumes, sulfur oxides (SO_x).

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. Do not spray water into the burning material.

6. 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.

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 15°-30° C (59°- 86° 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: Colorless, to slightly yellow solution with camphor like odor.

Boiling Point:	NE	Evaporation Rate:	NE
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Specific Gravity:	1.0	Vapor Density:	NE
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Vapor Pressure:	NE	Viscosity:	NE
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Water Solubility:	Soluble	Percent Volatile by Volume:	<1
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10. 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, sulfur oxides (SO_x).

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY

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 #

136-47-0

Tetracaine 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, coma. Should be avoided by individuals sensitive to other ester-type local anesthetics (e.g. benzocaine, butacaine, butamben, chlorocaine, tetracaine, propoxycaine) or PABA. IP-mice LD₅₀ 70 mg/Kg.

10043-35-3

Boric Acid

Inhalation can cause coughing and chest discomfort. Prolonged skin contact can cause burns and sensitization. Ingestion can cause nausea and vomiting. Swallowing large quantities may be fatal and chronic exposure can cause central nervous system stimulation and skin redness or rash. Oral-rat LD₅₀ 2660 mg/kg, Inhalation-rat LC₅₀ >16 mg/L.

12. ECOLOGICAL INFORMATION

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

13. DISPOAL 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

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. 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. 24208-920-64 (15ml)

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

16. OTHER INFORMATION

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.

NE- Not Established

< - Less Than

> - Greater Than