

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 020

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Pilocarpine Hydrochloride Ophthalmic Solution USP, 0.5%
Generic Name: Same
NDC No. 24208-806-15 (15 ml)

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

Drug Composition: Anticholinergic imidazoline derivative (Contracts pupil)

BAUSCH & LOMB PHARMACEUTICALS, INC.

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
Pilocarpine HCl	92-13-7	NE	NE	0.5
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Edetate Disodium, Hydroxypropyl Methylcellulose, Sodium Phosphate, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless, slightly viscous solution. May cause temporary difficulty adapting to darkness. Use caution while engaging in hazardous activities in poor light. Toxic by ingestion.

POTENTIAL HEALTH HAZARDS

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

Eye: This is an ophthalmic preparation. It may cause a temporary burning sensation, cause eye spasms (ciliary), swelling of the mucous membranes of the eye conjunctival vascular congestion), headache, tearing, and induced nearsightedness (myopia). These symptoms are more often seen in young persons recently starting administration. Reduced visual acuity is observed in older individuals or those with lens cloudiness (opacity). Miotic agents may cause retinal detachment especially in young myopic patients. Systemic reactions following topical administration have on rare occasion included hypertension, rapid heart rate (tachycardia), slow heart rate (bradycardia), bronchiolar spasm, pulmonary edema, salivation, sweating, confusion, nausea, vomiting, and diarrhea.

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: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can induce systemic symptoms. (See Eye).

Inhalation: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Aspiration of a liquid preparation is not likely.

Chronic Effects: Lens cloudiness can result from prolonged use. No long term studies have been conducted to evaluate the carcinogenic potential of pilocarpine hydrochloride.

Target Organs: Eyes, heart, digestive and respiratory tract.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product. Pilocarpine HCl is not recommended where miosis is undesirable such as acute iritis or pupillary block glaucoma. It is not known whether the drug is excreted in human milk, so caution should be exercised when pilocarpine is administered to a nursing woman. Aggravation of symptoms

may occur for patients with bradycardia, bronchial asthma, cardiac disease, epilepsy, hypotension, Parkinsonism, or peptic ulceration.

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: Miotic agents may cause retinal detachment especially in young myopic patients. Systemic reactions following topical administration have on rare occasion included hypertension, rapid heart rate (tachycardia), slow heart rate (bradycardia) bronchiolar spasm, pulmonary edema, salivation, sweating, nausea, vomiting, and diarrhea. Aggravation of symptoms may occur for patients with bradycardia, bronchial asthma, cardiac disease, epilepsy, hypotension, Parkinsonism, or peptic ulceration. 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: Nitrogen oxides (NO_x), Hydrogen Chloride gas (HCl) and 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.

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 15⁰-30⁰ C (59⁰- 86⁰ 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 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 slightly viscous solution.

Boiling Point: NE

Evaporation Rate: NE

Specific Gravity: 1.0

Vapor Density: NE

Vapor Pressure: NE

Viscosity: NE

Water Solubility: Miscible Percent Volatile by Volume: <1

10. STABILITY AND REACTIVITY

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: Nitrogen oxides (NO_x), Hydrogen Chloride gas (HCl) and toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

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 #

92-13-7 **Pilocarpine HCl, USP**

May cause irritation to the eyes, skin and respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals by contact with the eyes, skin, inhalation or ingestion. Poisoning may occur by skin absorption. Systemic effects of overexposure include sweating, headache, nausea, vomiting, tearing, nasal discharge, gas (eructation), uncontrolled defecation and urination, fear, excessive dreaming, excessive contraction of the pupils (miosis), congestion of the eye (conjunctiva), visual disturbances, airway constriction and secretion (bronchiole), slow heart rate (bradycardia), low blood pressure (hypotension), and coma. Death may occur due to cardiac arrest, respiratory paralysis, and/or pulmonary edema. Medical conditions aggravated by pilocarpine hydrochloride include individuals with slow heart rate, cardiac disease, low blood pressure, bronchial asthma, epilepsy or stomach ulcers. Oral-mouse LD₅₀ 200 mg/kg, Intravenous-guinea pig LD₅₀ 20 mg/kg.

12. ECOLOGICAL INFORMATION

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

13. 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

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. 24208-806-15 (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

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
Than

< - Less Than

> - Greater