BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	10/13/03		Manager EHS
Revision:	03	Core No. 053	

1. PRODUCT AND COMPANY INFORMATION

Product Name: Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5%
Generic Name: Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5%
NDC No. 24208-740-59 (2 ml)
24208-740-02 (5 ml)
24208-740-06 (15 ml)

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

Drug Composition: Mydriatic (opens pupils) & vasoconstrictor

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
Phenylephrine HCL	61-76-7	NE	NE	2.5
Boric Acid	10043-35-3	NE	NE	$\geq$1
Purified Water	7732-18-5	NE	NE	$\geq$1

Ingredients <1% - Sodium Borate, Edetate Disodium, Sodium Bisulfite, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless to slightly yellow, aqueous solution. Do not use if solution is brown color or contains a precipitate. Patients with insulin-dependent diabetes, hypertension, hyper-thyroidism, generalized arteriosclerosis, cardiac disease, asthma and the elderly may be more susceptible to systemic effects. For eyes only. Presents little or no hazards if spilled and no unusual hazard if involved in fire.

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POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation, a burning sensation and cause hypersensitivity (anaphylactic) in some individuals. Can cause headache, irregular heart rate, increase in blood pressure and dizziness. Persons with cardiac diseases and asthma may be more susceptible to systemic side effects.

Skin: May cause irritation and hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause headache, irregular heart rate, increase in blood pressure, tremor, perspiration, pallor, vomiting, dizziness and collapse.

Inhalation: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Inhalation of a liquid preparation is not likely. Evaporation is minimal at controlled room temperatures.

Chronic Effects: Repeated and prolonged exposure may cause hypersensitivity in some individuals.

Target Organs: Eyes and heart.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product. Persons hypersensitive to other sympathomimetics (amphetamines, ephedrine, epinephrine, isoproterenol, metaproterenol, norepinephrine, phenylpropanolamine, pseudoephedrine, terbutaline) may be hypersensitive to phenylephrine hydrochloride. Any mydriatic is usually not indicated for patients with narrow angle glaucoma. Contains sodium bisulfite which may cause allergic type reactions including anaphylactic symptoms and also threatening or less severe asthmatic episodes in certain susceptible people.

The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than non-asthmatic people. There have been rare reports associating the use of phenylephrine hydrochloride 10 percent ophthalmic solutions with the development of serious cardiovascular reactions, including ventricular arrhythmias and myocardial infarctions. These episodes, some ending fatally, have usually occurred in elderly persons with preexisting cardiovascular diseases. A significant elevation in blood pressure is rare, but has been reported, following installation into the eye the recommended doses of phenylephrine hydrochloride 10 percent ophthalmic solutions. Caution should be exercised in administering the 10 percent solutions to children of low body weight, the elderly, and patients with insulin-dependent diabetes, hypertension, hyperthyroidism, generalized arteriosclerosis, or cardiovascular disease. Animal reproduction studies have not been done with phenylephrine hydrochloride. It is not known if phenylephrine hydrochloride ophthalmic solutions can cause fetal harm when given to a pregnant woman or if it is excreted in breast milk.

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: Phenylephrine is a sympathomimetic drug related to epinephrine and ephedrine; although it is rare, it may produce such reactions as tremor, pallor, perspiration, abnormal palpitation, or collapse. Additional details are available on the package insert or in the Physicians Desk Reference.

Pregnancy: Animal reproduction studies have not been conducted with phenylephrine hydrochloride ophthalmic solutions. It is also not known whether phenylephrine hydrochloride ophthalmic solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Phenylephrine hydrochloride ophthalmic solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not know if whether this drug is excreted is excreted in milk; many are. Caution should be exercised when phenylephrine hydrochloride ophthalmic solution is administered to a nursing woman.

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: 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.

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 under refrigerated condition, at approximately 2°C – 8°C (36°F - 46°F). Do not Freeze. **KEEP THIS AND ALL OTHER 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 to slightly yellow solution		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Complete	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: Emits toxic fumes.

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 #

61-76-7 **Phenylephrine HCl**
May cause local irritation of the eye, skin, and respiratory tract. Can cause headache, dizziness, trembling, dizziness, increased heart rate and blood pressure, nervousness, pallor, and cold sweats. Can cause hypersensitivity (anaphylactic) in some individuals. Persons with hypersensitivity to other sympathomimetics (amphetamines, ephedrine, epinephrine, isoproterenol, metaproterenol, norepinephrine, phenylpro-panolamine, pseudoephedrine, terbutaline) may be hypersensitive to phenylephrine hydrochloride. Animal reproduction studies have not been done with phenylephrine hydrochloride. It is not known if phenylephrine hydrochloride ophthalmic solutions can cause fetal harm when given to a pregnant woman or if it is excreted in breast milk.

10043-35-3 **Boric Acid**
May cause irritation to the eyes, skin, respiratory and digestive tract. Inhalation may cause coughing and chest discomfort. Prolonged skin contact may cause burns and sensitization. Ingestion may cause nausea and vomiting and swallowing large quantities may be fatal. Chronic exposure may cause central nervous system stimulation and skin redness or rash. Oral-rat LD_{50} 2660 mg/kg, Inhalation-rat LC_{50} >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. 24208-740-59 (2 ml)
NDC No. 24208-740-02 (5 ml)
NDC No. 24208-740-06 (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

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