

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

Issued: 09/07/94  
Revised: 12/20/01  
Revision: 02

Prepared by: Gary Wong  
Manager EHS  
Core No. 278

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Dipivefrin Hydrochloride Ophthalmic Solution USP, 0.1%  
**Generic Name:** Same  
**NDC No.** 24208-540-05 ( 5 ml)  
24208-540-10 (10 ml)  
24208-540-15 (15 ml)

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

**Drug Composition:** Adrenergic prodrug (Antiglaucoma)

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 <sup>3</sup> )	PEL(mg/m <sup>3</sup> )	% Content
Dipivefrin HCL	64019-93-8	NE	NE	0.1
Purified Water	7732-18-5	NE	NE	≥1

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

---

### 3. HAZARDS IDENTIFICATION

---

\*\*\*\*\*

#### EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. White, aqueous solution.

\*\*\*\*\*

#### POTENTIAL HEALTH HAZARDS

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

**Eye:** May cause irritation, burning or stinging on installation. Can cause hypersensitivity (anaphylactic) in some individuals. Large doses could cause convulsions, rapid heart beat, increased blood pressure and impaired muscular coordination. APHAKIC PATIENTS: 30% of all patients missing the crystalline lens of the eye develop a reversible diffuse swelling with the use of epinephrine.

**Skin:** May cause irritation and hypersensitivity in some individuals.

**Ingestion:** May cause irritation and hypersensitivity in some individuals. Large doses could cause convulsions, rapid heart beat, increased blood pressure and impaired muscular coordination.

**Inhalation:** May cause irritation and hypersensitivity in some individuals. Vapors produced at controlled room temperature are negligible.

**Chronic Effects:** May cause hypersensitivity. Rabbit studies indicated a dose related incidence of meibomian gland retention cysts following topical administration of both dipivefrin and epinephrine.

**Target Organs:** Eyes, heart and nervous system.

**Medical Conditions Aggravated by Long Term Exposure:** Hypersensitivity to any of the components of the product. \* Reproduction studies have been performed in rats and rabbits at daily oral doses up to 10 mg/g body weight (5 mg/Kg in teratogenicity studies), and have revealed no evidence of impaired fertility or harm to the fetus due to dipivefrin. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

- It is not known if this drug is excreted in human milk, so caution should be exercised when administering this or any drug to a nursing mother.
- Clinical and efficacy studies in children have not been done.

---

#### 4. FIRST AID MEASURES

---

**Eyes:** If not prescribed this medication, 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 give plenty of water and bland fluids. Seek professional assistance.

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

**Note to Physicians:** None.

---

#### 5. FIRE FIGHTING MEASURES

---

**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** 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. 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<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<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 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:	White, aqueous 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 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 #

64019-93-8

**Dipivefrin HCL**

May cause irritation and hypersensitivity (anaphylactic) in some individuals. Potent drug which converts to epinephrine in the human body. Overexposure can induce tachycardia, arrhythmias, and hypertension. May cause convulsions and impaired muscular coordination (ataxia). Oral-rat LD<sub>50</sub> 183 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. 24208-540-05 ( 5 ml)  
NDC No. 24208-540-10 (10 ml)  
NDC No. 24208-540-15 (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.

NA – Not Applicable

NE- Not Established

< - Less Than

> - Greater Than