

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

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### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** MUROCOLL<sup>®</sup> 2  
**Generic Name:** Phenylephrine Hydrochloride 10% and Scopolamine Hydrobromide 0.3% Ophthalmic Solution  
**NDC No.** 24208-278-05 (5ml)  
**Legal Category:** Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.  
**Drug Composition:** Mydriatic, vasoconstrictor/ mydriatic, cycloplegic (Opens pupil & paralyzes light accommodation)

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
Phenylephrine HCL	61-76-7	NE	NE	2.5
Scopolamine HBr	114-49-8	NE	NE	0.3
Citric Acid	77-92-9	NE	NE	≥1
Sodium Phosphate	7558-79-4	NE	NE	≥1
Purified Water	7732-18-5	NE	NE	≥1

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

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless to slightly yellow aqueous solution. Do not engage in hazardous activity while under the influence. Protect eyes from bright light while dilated. Toxic by ingestion. For eyes only.

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#### POTENTIAL HEALTH HAZARDS

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

**Eye:** May cause irritation and burning sensation. Redness usually occurs which is a normal therapeutic response. Headache frequently occurs but will usually diminish with continued treatment. Can cause hypersensitivity (anaphylactic) in some individuals. Systemic effects include anxiety, fear, irregular heart rate, increase in blood pressure, dizziness, trembling, sweating and pallor. Patients with insulin-dependent diabetes, hypertension, hyper-thyroidism, generalized arteriosclerosis, cardiac disease, asthma, infants and the elderly may be more susceptible to systemic effects.

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

**Ingestion:** Toxic by ingestion. May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can 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.

**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

metabisulfite 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 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.

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#### 4. FIRST AID MEASURES

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**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:**

- Phenylephrine is a sympathomimetic drug related to epinephrine and ephedrine, and though it is rare, it may produce such reactions as tremor, pallor, perspiration, abnormal palpitation or collapse.
- Phenylephrine HCL 10 percent solutions are contraindicated in infants.
- Drug interactions between sympathomimetic amines and monoamine oxidase (MOA) inhibitors may result in a marked increase in blood pressure and hypertensive crisis if used concomitantly.

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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 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.

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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.

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## 7. HANDLING AND STORAGE

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**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.**

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## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

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**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.

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## 9. CHEMICAL & PHYSICAL PROPERTIES

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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

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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:** Emits toxic fumes.

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY INFORMATION

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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 #

61-76-7

### Phenylephrine HCL

May cause local irritation of the eye, skin, and respiratory tract. Can cause headache, dizziness, trembling, 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, phenylpropanolamine, 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.

114-49-8                      **Scopolamine HBr**

May cause irritation and hypersensitivity in some individuals. Very toxic by eye, skin, ingestion and inhalation. Anticholinergic causes drowsiness and central nervous system depression. Oral-rat LD<sub>50</sub> 1270 mg/kg.

77-92-9                      **Citric Acid**

May cause irritation to the eyes and respiratory tract. Mild irritant to the skin. Naturally occurring compound in plant and animal tissues. Generally recognized as safe in foods. Chronic oral over exposure can cause tooth enamel damage. Oral-rat LD<sub>50</sub> 11,700 mg/kg. Severe irritation eye 750 mg/24 hr.

7558-79-4                      **Sodium Phosphate**

May cause irritation to the eyes, mucous membrane, skin, respiratory and digestive tract. Skin contact can cause blistering, pain and burns. Eye contact can induce pain and corneal injury. Ingestion may result in pain, vomiting, diarrhea, shock, hypotension, cyanosis, slow pulse, coma and possibly death. Oral-rat LD<sub>50</sub> 12930 mg/kg (heptahydrate).

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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. DISPOSAL 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. 24208-278-05 (5ml)
- 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.

NA - Not Applicable  
NE - Not Established  
< - Less Than  
> - Greater Than