

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

Issued: 10/13/94  
Revised: 02/05/02  
Revision: 01

Prepared by: Gary Wong  
Manager EHS  
Core No. 307

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** CROLOM®  
**Generic Name:** Cromolyn Sodium Ophthalmic Solution USP, 4%  
**NDC No.** 24208-300-10 (10 ml)

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

**Drug Composition:** Antiallergenic (Mast cell stabilizer)

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
Cromolyn Sodium	15826-37-6	NE	NE	4.0
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Edetate Disodium, Benzalkonium Chloride

---

### 3. HAZARDS IDENTIFICATION

---

\*\*\*\*\*

#### EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless 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. Adverse reactions which have been reported as infrequent effects include conjunctival injection, watery eyes, itchy eyes, dryness around the eye, puffy eyes, eye irritation and styes. It is unclear if these effects are attributable to the drug. As with all ophthalmic drugs containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment with cromolyn sodium ophthalmic solution.

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

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

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

**Chronic Effects:** May cause hypersensitivity. Prolonged use can cause conjunctival injection, watery eyes, itchy eyes, dryness around the eye, puffy eyes, eye irritation and styes. It is unclear if these effects are attributable to the drug.

**Target Organs:** Eyes.

**Medical Conditions Aggravated by Long Term Exposure:** Hypersensitivity to any of the components of the product.

- Reproduction studies have been performed in rats, mice and rabbits up to 338 times the human clinical doses with no evidence of fetal malformations. Adverse fetal effects (increased resorption and decreased fetal weight) were noted only at the very high parental doses that produced maternal toxicity. 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.
- Fertility studies of animals show no impaired fertility.
- Mutagenesis studies of animals show no evidence of chromosomal damage.

- 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 below the age of 4 years 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. Contact a physician.

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

**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

**Flammable Limits:** Lower Flammable Limit: NE Upper Flammable Limit: NE

**Autoignition Temperature:** 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.

---

#### 6. ACCIDENTAL RELEASE MEASURES

---

**Large/Small Spills:** Notify your supervisor immediately. Minimize contact with spilled material. Keep other personnel away from the clean up area. Wear appropriate respiratory protection. Wear approved respirator and chemically compatible gloves. Use personal protective equipment. (Refer to Section 8)

Squeegee, scoop, absorb or use a vacuum to clean up spill. Clean area with an alkaline cleaner/detergent. Dispose of waste material in accordance with Federal, State and Local regulations.

While not a RCRA hazardous waste, material should be disposed of according to Federal, State and Local regulations. Incineration is the preferred disposal method.

---

## 7. HANDLING AND STORAGE

---

This material should be handled and stored per label and other instructions to ensure product integrity.

**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. Provide adequate local exhaust ventilation.

**Hygienic Practices:** Train employees concerning hazards and precautions.

Wash hands and forearms after each use and use recommended personal protective equipment while handling.

**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 aqueous solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Melting Point:	1.0E	Vapor Density:	NE
Vapor Pressure:	NE	Specific Gravity:	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 #

15826-37-6                      **Cromolyn Sodium**

May cause irritation to the mucous membranes of the eyes, skin or respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals. Adverse effects include throat irritation or dryness, bronchospasm, wheezing, coughing, nausea, vomiting, headache and dizziness. Subcutaneous-mouse LD<sub>50</sub> 4400 mg/Kg, Intravenous-mouse LD<sub>50</sub> 3300 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. 24208-300-10 (10 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