

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Cromolyn Sodium Ophthalmic Solution, 4%

Product Description • Ophthalmic solution for eyes. Prescription pharmaceutical product.

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finished Pharmaceutical Product; See package insert for complete directions for use and important safety information.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications. KEEP OUT OF REACH OF CHILDREN

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb, Inc

1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Eye Mild Irritation 2B
Skin Mild Irritation 3

Label elements

UN GHS

WARNING

Hazard statements • Causes eye irritation
Causes mild skin irritation

Precautionary statements

Prevention • Wash thoroughly after handling.

Response • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • KEEP OUT OF REACH OF CHILDREN
Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Cromolyn sodium	CAS:15826-37-6 EINECS:239-926-7	4%	UN GHS: NDA
Benzalkonium chloride	CAS:8001-54-5	0.01%	UN GHS: Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3
Edetate disodium hydrate	CAS:6381-92-6	< 1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: NDA

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media

- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- None known.

Hazardous Combustion Products

- None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures

- Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13. Keep unauthorized personnel away. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Incompatible Materials or Ignition Sources

- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use.

Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description

Physical Form	Liquid	Appearance/Description	Not relevant
Color	Clear Colorless .	Odor	Not relevant
Odor Threshold	Not relevant	Physical and Chemical Properties	Solution

General Properties

Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	= 1.019	Water Solubility	Not relevant
Solvent Solubility	Not relevant	Viscosity	Not relevant

Volatility

Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant	VOC (Wt.)	Not relevant
VOC (Vol.)	Not relevant		

Flammability

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not flammable.		

Environmental

Octanol/Water Partition coefficient	Not relevant		
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Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Cromolyn sodium (4%)	15826-37-6	Acute Toxicity: Ingestion/Oral-Mouse LD50 • >11 g/kg; Ingestion/Oral-Woman TDLo • 96 mg/kg 6 Day(s)-Intermittent; Skin and Appendages: After systemic exposure: Dermatitis, allergic
Benzalkonium chloride (0.01%)	8001-54-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 240 mg/kg; Behavioral: Somnolence (general depressed activity) ; Gastrointestinal: Nausea or vomiting ; Irritation: Eye-Rabbit • 1 mg 24 Hour(s) • Severe irritation; Skin-Rabbit • 50 mg 24 Hour(s) • Moderate irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 274 g/kg 2 Year(s)-Continuous; Behavioral: Food intake (animal) ; Nutritional and Gross Metabolic: Gross Metabolite Changes: Weight loss or decreased weight gain ; Related to Chronic Data: Death in the Other Multiple Dose data type field

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Classification criteria not met; Acute Toxicity - Dermal - Classification criteria not met; Acute Toxicity - Inhalation - Classification criteria not met; Acute Toxicity - Oral - Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B

Potential Health Effects

Inhalation

- Acute (Immediate)
- Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)
- No data available.

Skin

- Acute (Immediate)
- May cause mild irritation.
- Chronic (Delayed)
- Repeated and prolonged exposure may cause irritation.

Eye

Acute (Immediate)

- May cause mild irritation.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.

Ingestion**Acute (Immediate)**

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available.

Section 12 - Ecological Information**Toxicity**

Component	CAS	Data	Comments
Benzalkonium chloride (0.01%)	8001-54-5	Fish: 96 Hour(s) LC50 Fish <i>Pimephales promelas</i> 0.28 mg/L	

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
ADN	NDA	Not regulated	NDA	NDA	NDA
ADR/RID	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Other information

- Transportation labeling and compliance with applicable laws are the responsibility of the shipper.

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Cromolyn sodium	15826-37-6	Yes	Yes	No
Edetate disodium hydrate	6381-92-6	Yes	No	No
Benzalkonium chloride	8001-54-5	Yes	No	No

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Edetate disodium hydrate	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium chloride	8001-54-5	D1B, E
• Cromolyn sodium	15826-37-6	Not Listed

Germany

Labor

Germany - TRGS 511 - Specific Ammonium Nitrate Regulations

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed

• Cromolyn sodium	15826-37-6	Not Listed
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United States - South Carolina

Environment

U.S. - South Carolina - Drinking Water Regulations - Maximum Contaminant Levels (MCLs)

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

U.S. - South Carolina - Toxic Air Pollutants - Maximum Allowable Concentrations

• Edetate disodium hydrate	6381-92-6	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Cromolyn sodium	15826-37-6	Not Listed

Section 16 - Other Information

Last Revision Date	• 22/January/2015
Preparation Date	• 22/January/2015
Disclaimer/Statement of Liability	• No data available