



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Cromolyn Sodium Nasal Solution**
Product Code • Core No. 397; ET39753

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

- Recommended use** • Nasal allergy symptom controller
Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
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 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

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** • Skin Mild Irritation 3
Eye Mild Irritation 2B

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 tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride	CAS:63449-41-2 EINECS:264-151-6	< 0.1%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Cromolyn Sodium	CAS:15826-37-6 EINECS:239-926-7	4%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 90%	UN GHS: Not Classified

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- 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 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

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**

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

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	Color	Not relevant
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	No data available
Specific Gravity/Relative Density	= 1.016	Water Solubility	water soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Burning Rate Test	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

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
Benzalkonium Chloride (< 0.1%)	63449-41-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg; Behavioral: Somnolence (general depressed activity); Blood: Hemorrhage

GHS Properties	Classification
Acute toxicity	UN GHS • 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)

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

Chronic (Delayed)

- No data available.

Skin

Acute (Immediate)

- May cause mild irritation.

Chronic (Delayed)

- Repeated and prolonged exposure may cause irritation.

Eye

- Acute (Immediate)** • Causes eye irritation.
- Chronic (Delayed)** • No data available

Ingestion

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

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

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** • Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
- 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
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

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 Dihydrate	139-33-3	Yes	Yes	Yes
Benzalkonium Chloride	63449-41-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Cromolyn Sodium	15826-37-6	Not Listed

Europe**Other****EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	C N R:21/22-34-50 S:(2)-36/37/39-45-61
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	S:(2)-36/37/39-45-61
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

United States - California

Environment

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

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

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Water	7732-18-5	Not Listed
• Cromolyn Sodium	15826-37-6	Not Listed

Section 16 - Other Information

Last Revision Date

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Preparation Date

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