



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Advanced Eye Relief™ Redness Instant Relief Lubricant/Redness Reliever Eye Drops**

Product Code • AB55811; FCP-4002

Product Description • Ophthalmic solution for eyes.

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

Recommended use • OTC redness relief

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

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 • Skin Mild Irritation 3

Label elements

UN GHS

WARNING

Hazard statements • Causes mild skin irritation

Precautionary statements

Response • If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Store at 15-25°C (59-77°F)..
Keep tightly closed and store in upright position.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 2%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Sodium borate	CAS:1303-96-4	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2
Polyethylene glycol #300	CAS:25322-68-3	0.2%	UN GHS: not classified
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Naphazoline hydrochloride	CAS:550-99-2 EINECS:208-989-2	0.012%	UN GHS: not classified
Benzalkonium chloride	CAS:8001-54-5	0.01%	UN GHS: Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3
Edetate disodium	CAS:6381-92-6	< 0.1%	UN GHS: not classified
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 95%	UN GHS: not classified

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.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Get medical attention if symptoms occur. No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- IF ON SKIN: Wash with plenty of soap and water. 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 • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

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. Refer to Section 8.

Emergency Procedures • No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

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.

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.

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.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines				
	Result	ACGIH	Canada Quebec	NIOSH
Sodium borate	TWAs	2 mg/m ³ TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m ³ TWAEV	5 mg/m ³ TWA

(1303-96-4)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established

Exposure Control Notations**ACGIH**

- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))
- Sodium borate (1303-96-4): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

Exposure Limits Supplemental**ACGIH**

- Boric acid (10043-35-3): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (listed under Borate compounds, inorganic))
- Sodium borate (1303-96-4): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (listed under Borate compounds, inorganic))

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 respiratory protection required during normal handling.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Wear protective eyewear (goggles, face shield, or safety glasses).

Hands

- Wear protective gloves .

Skin/Body

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

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid	Color	Colorless to pale yellow.
Odor	No odor.		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	6 to 6.3
Specific Gravity/Relative Density	= 1.008	Water Solubility	Not relevant
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

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

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Boric acid (< 2%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; Behavioral:Convulsions or effect on seizure threshold; Behavioral:Ataxia; Reproductive: Ingestion/Oral-Rat TDLo • 1600 mg/kg (6-9D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system</i> ; Ingestion/Oral-Rat TDLo • 76 mg/kg (20D preg); <i>Reproductive Effects:Effects on Embryo or Fetus:Fetotoxicity (except death, e.g., stunted fetus)</i>
Sodium borate (< 0.1%)	1303-96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 70 g/kg (90D male); <i>Reproductive Effects:Paternal Effects:Testes, epididymis, sperm duct</i> ; Ingestion/Oral-Rat TDLo • 70 g/kg (90D pre); <i>Reproductive Effects:Maternal Effects:Ovaries, fallopian tubes</i> ; Ingestion/Oral-Rat TDLo • 37 g/kg (multigenerations); <i>Reproductive Effects:Effects on Newborn:Weaning or lactation index</i>
Polyethylene glycol #300 (0.2%)	25322-68-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 28 g/kg
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Ingestion/Oral-Rat TDLo • 1 mg/kg 24 Hour(s); <i>Biochemical:Metabolism (intermediary):Effect on Na-K pump</i>
Naphazoline hydrochloride (0.012%)	550-99-2	Acute Toxicity: Ingestion/Oral-Rabbit LD50 • 50 mg/kg; <i>Lungs, Thorax, or Respiration:Respiratory stimulation</i>
Benzalkonium chloride (0.01%)	8001-54-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 240 mg/kg; Behavioral:Somnolence (general depressed activity); <i>Gastrointestinal:Nausea or vomiting;</i> Irritation: Skin-Rabbit • 50 mg 24 Hour(s) • Moderate irritation

GHS Properties	Classification
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Acute toxicity	UN GHS • Acute Toxicity - 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 • Classification criteria not met

Potential Health Effects

Inhalation

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

Skin

- Acute (Immediate)**
 - May cause mild irritation.
- Chronic (Delayed)**
 - Causes mild skin irritation.

Eye

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

Ingestion

- Acute (Immediate)**
 - Small amounts (a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Chronic (Delayed)**
 - No data available

Carcinogenic Effects		
	CAS	NTP
Boric acid	10043-35-3	Evidence of Carcinogenicity

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
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

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
Naphazoline hydrochloride	550-99-2	Yes	Yes	No
Edetate disodium	6381-92-6	Yes	No	No
Benzalkonium chloride	8001-54-5	Yes	No	No
Sodium borate	1303-96-4	Yes	No	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Polyethylene glycol #300	25322-68-3	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Purified water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

- Sodium borate

1303-96-4

D2B

Uncontrolled product

• Edetate disodium	6381-92-6	according to WHMIS classification criteria
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium chloride	8001-54-5	D1B, E
• Boric acid	10043-35-3	D2A
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyethylene glycol #300	25322-68-3	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Sodium borate	1303-96-4	1 %
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	1 %
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	Repr.Cat.2; R60-61
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	8.5%≤C: Repr.Cat.2; R:60-61
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	T R:60-61 S:53-45
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	S:53-45
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	S:53-45
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Naphazoline hydrochloride	550-99-2	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyethylene glycol #300	25322-68-3	Not Listed

Section 16 - Other Information

Last Revision Date

- 06/February/2015

Preparation Date

- 30/January/2015

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