



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • **ADVANCED EYE RELIEF™ Dry Eye Rejuvenation Lubricant Eye Drops**
- Product Code** • 622003; 622010; FCP-4138
- Product Description** • Dry eye therapy.

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

- Recommended use** • Relieves dryness of the eye
- Restrictions on use** • Use in accordance with product literature.

#### 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 - Infotrac

### 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** • Classification criteria not met

#### Label elements

**UN GHS**

#### Precautionary statements

- 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

- 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:8001-54-5	0.01%	UN GHS: Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Edetate disodium	CAS:6381-92-6	< 0.1%	UN GHS: not classified
Glycerin	CAS:56-81-5 EINECS:200-289-5	0.3%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Potassium chloride	CAS:7447-40-7 EINECS:231-211-8	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT RE 1
Propylene glycol	CAS:57-55-6 EINECS:200-338-0	1%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 95%	UN GHS: not classified
Sodium borate	CAS:1303-96-4	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5

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

- 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

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

#### Eye

- No specific treatment is necessary since this material is not irritating to the eye.

#### 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 expiration date marked on carton and on container. KEEP OUT OF THE REACH OF CHILDREN.

## 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	OSHA
Sodium borate	TWAs	2 mg/m <sup>3</sup> TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m <sup>3</sup> TWAEV	5 mg/m <sup>3</sup> TWA	Not established

(1303-96-4)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established	Not established
Glycerin (56-81-5)	TWAs	Not established	10 mg/m3 TWA EV (mist)	Not established	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	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	Clear Colorless .
Odor	No odor.		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	7.1 to 7.5
Specific Gravity/Relative Density	= 1.002	Water Solubility	Not relevant

Viscosity	No data available		
<b>Volatility</b>			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
<b>Flammability</b>			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
<b>Environmental</b>			
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 (< 1%)	10043-35-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2500 mg/kg; <b>Behavioral:</b> <b>Convulsions or effect on seizure threshold; Ataxia;</b> <b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 1600 mg/kg (6-9D preg); <b>Reproductive Effects:</b> <i>Specific Developmental Abnormalities:</i> <b>Musculoskeletal system;</b> Ingestion/Oral-Rat TDLo • 76 mg/kg (20D preg); <b>Reproductive Effects:</b> <i>Effects on Embryo or Fetus:</i> <b>Fetotoxicity (except death, e.g., stunted fetus)</b>
Sodium borate (< 0.1%)	1303-96-4	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2660 mg/kg; <b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 70 g/kg (90D male); <b>Reproductive Effects:</b> <i>Paternal Effects:</i> <b>Testes, epididymis, sperm duct;</b> Ingestion/Oral-Rat TDLo • 70 g/kg (90D pre); <b>Reproductive Effects:</b> <i>Maternal Effects:</i> <b>Ovaries, fallopian tubes;</b> Ingestion/Oral-Rat TDLo • 37 g/kg (multigenerations); <b>Reproductive Effects:</b> <i>Effects on Newborn:</i> <b>Weaning or lactation index</b>
Sodium chloride (< 1%)	7647-14-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3000 mg/kg; Ingestion/Oral-Rat TDLo • 1 mg/kg 24 Hour(s); <b>Biochemical:</b> <i>Metabolism (intermediary):</i> <b>Effect on Na-K pump</b>
Benzalkonium chloride (0.01%)	8001-54-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 240 mg/kg; <b>Behavioral:</b> <b>Somnolence (general depressed activity);</b> <b>Gastrointestinal:</b> <b>Nausea or vomiting;</b> <b>Irritation:</b> Skin-Rabbit • 50 mg 24 Hour(s) • Moderate irritation
Glycerin (0.3%)	56-81-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 12600 mg/kg; <b>Behavioral:</b> <b>General anesthetic;</b> <b>Behavioral:</b> <b>Muscle weakness;</b> <b>Liver:</b> <b>Other changes;</b> <b>Irritation:</b> Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation; <b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 100 mg/kg (1D male); <b>Reproductive Effects:</b> <i>Effects on Fertility:</i> <b>Post-</b>

		implantation mortality
Potassium chloride (< 1%)	7447-40-7	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2600 mg/kg; <b>Irritation:</b> Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; <b>Mutagen:</b> Unscheduled DNA synthesis • Ingestion/Oral-Rat • 1500 µg/kg
Propylene glycol (1%)	57-55-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 20 g/kg; <b>Irritation:</b> Eye-Rabbit • 100 mg • Mild irritation; Skin-Human • 104 mg 3 Day(s)-Intermittent • Moderate irritation

GHS Properties	Classification
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 • Classification criteria not met
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)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

### 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	NDA	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	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
Propylene glycol	57-55-6	Yes	Yes	Yes
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
Glycerin	56-81-5	Yes	Yes	Yes
Potassium chloride	7447-40-7	Yes	Yes	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 according to WHMIS classification criteria (including 23.8%)
• Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Glycerin	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Edetate disodium	6381-92-6	Uncontrolled product 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
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

#### Canada - WHMIS - Ingredient Disclosure List

• Sodium borate	1303-96-4	1 %
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	1 %
• Glycerin	56-81-5	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	1 %
• Purified water	7732-18-5	Not Listed

## Europe

### Other

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

• Sodium borate	1303-96-4	Repr.Cat.2; R60-61
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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	Repr.Cat.2; R60-61
• Purified water	7732-18-5	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
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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	5.5%≤C: Repr.Cat.2; R:60-61
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	T R:60-61 S:53-45
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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	T R:60-61 S:53-45
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	S:53-45
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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	S:53-45
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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
• Purified water	7732-18-5	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Potassium chloride	7447-40-7	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Glycerin	56-81-5	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
• Purified water	7732-18-5	Not Listed

**Section 16 - Other Information****Last Revision Date**

- 06/February/2015

**Preparation Date**

- 06/February/2015

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