

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Soothe® Long Lasting**
- Synonyms** • PVP Tears Ophthalmic Solution
- Product Code** • 622219; AB54411; Core 544; FCP-4266
- Product Description** • Dry eye therapy.
• Lubricant eye drops.

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

- Recommended use** • Relieves dryness of the eye, prevents further irritation
- Restrictions on use** • Do not use if solution changes color or becomes cloudy; Remove contact lenses before using; Stop use and ask a doctor if: you experience eye pain, changes in vision, continued redness or irritation of the eye, or if condition worsens or persists for more than 72 hours.

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

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** • Classification criteria not met

Label elements

UN GHS

Classification criteria not met

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	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 5%	Ingestion/Oral-Rat LD50 • 2660 mg/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1	NDA
Sodium Borate	CAS:1330-43-4 EINECS:215-540-4	< 5%	Ingestion/Oral-Rat LD50 • 2660 mg/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT SE 2	NDA
Povidone	CAS:9003-39-8	< 5%	NDA	UN GHS: NDA	NDA
Tyloxapol	CAS:25301-02-4	< 0.1%	Ingestion/Oral-Rat LD50 • >5 g/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A	NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 0.1%	Ingestion/Oral-Rat LD50 • 3 g/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5	NDA
Edetate Disodium	CAS:6381-92-6	< 0.1%	NDA	UN GHS: NDA	NDA
Benzalkonium chloride	CAS:8001-54-5	0.005%	Ingestion/Oral-Rat LD50 • 240 mg/kg	UN GHS: Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3	NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 90%	Ingestion/Oral-Rat LD50 • >90 mL/kg	UN GHS: NDA	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.

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 if cough or other symptoms develop.

Skin

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

Eye

- If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

Ingestion

- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- Stop use and ask a doctor if: you experience eye pain, changes in vision, continued redness, irritation of the eye, or if condition worsens or persists for more than 72 hours.

Indication of any immediate medical attention and special treatment needed

Other information

- Additional details are provided on the product packaging and/or the product insert.

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.

Firefighting Procedures ● As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards ● None known.

Hazardous Combustion Products ● None known.

Advice for firefighters

- Refer to Section 5 Firefighting Procedures.

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

Environmental precautions

- No data available on the environmental impact of this product.

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.

Prohibited Materials ● None known.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling ● When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after

use. 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.
- Special Packaging Materials**
- Maintain product in original container only.

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	Germany DFG	NIOSH
Sodium Borate (1330-43-4)	STELs	6 mg/m ³ STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m ³ TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	1 mg/m ³ TWA
Boric acid (10043-35-3)	STELs	6 mg/m ³ STEL (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m ³ TWA (inhalable fraction, listed under Borate compounds, inorganic)	Not established	Not established
	Ceilings	Not established	10 mg/m ³ Peak (inhalable fraction, as B)	Not established
	MAKs	Not established	10 mg/m ³ TWA MAK (inhalable fraction, as B)	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 (1330-43-4): **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 (1330-43-4): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (listed under Borate compounds, inorganic))

Exposure controls

Engineering Measures/Controls

- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. 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.
- Thermal hazards**
 - None known.
- General Industrial Hygiene Considerations**
 - Wash thoroughly with soap and water after handling.
- Environmental Exposure Controls**
 - No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Water-like
Color	Clear	Odor	No odor.
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	8.3
Specific Gravity/Relative Density	1.013 gm/ml	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Bioaccumulation Factor	No data available	Bioconcentration Factor	No data available
Biochemical Oxygen Demand BOD/BOD5	No data available	Chemical Oxygen Demand	No data available
Degradation	No data available		

Other Information

- No additional physical and chemical parameters noted.

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored at room temperature 15-25°C (59-77°F). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information**Information on toxicological effects**

Components		
Boric acid (< 5%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Sodium Borate (< 5%)	1330-43-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Tyloxapol (< 0.1%)	25301-02-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • >5 g/kg
Sodium chloride (< 0.1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3 g/kg
Benzalkonium chloride (0.005%)	8001-54-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 240 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Gastrointestinal:Nausea or vomiting</i>
Water (> 90%)	7732-18-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >90 mL/kg

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 • 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)** • No hazard when used as directed.
- Chronic (Delayed)** • No data available.

Skin

- Acute (Immediate)** • Non-irritating to skin or mucous membranes when used as directed.
- Chronic (Delayed)** • No data available.

Eye

- Acute (Immediate)** ● Non-irritating to the eyes when used as directed.
- Chronic (Delayed)** ● No data available.

Ingestion

- Acute (Immediate)** ● May be harmful if swallowed.
- Chronic (Delayed)** ● No data available.

Other

- Acute (Immediate)** ● May cause irritation.
- Chronic (Delayed)** ● No data available.

Mutagenic Effects

- No data available.

Carcinogenic Effects

- NTP: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by NTP. IARC: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by IARC. OSHA: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by OSHA.

Carcinogenic Effects			
	CAS	IARC	NTP
Boric acid	10043-35-3	Not Listed	Evidence of Carcinogenicity
Povidone	9003-39-8	Group 3-Not Classifiable	Not Listed

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** ● Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
- Packaging waste** ● Recycle

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 special precautions.

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
Edetate Disodium	6381-92-6	Yes	No	No
Benzalkonium chloride	8001-54-5	Yes	No	No
Boric acid	10043-35-3	Yes	Yes	Yes
Sodium Borate	1330-43-4	Yes	Yes	Yes
Tyloxapol	25301-02-4	Yes	No	No
Povidone	9003-39-8	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Povidone	9003-39-8	Uncontrolled product according to WHMIS classification criteria
• Sodium Borate	1330-43-4	Not Listed
• 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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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 %
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	4.5%≤C: 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	5.5%≤C: Repr.Cat.2; R60-61
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

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

• Povidone	9003-39-8	Not Listed
• Sodium Borate	1330-43-4	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
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed

Other Information

- Boric Acid (CAS 10043-35-3): REACH: PR, SVHC: Yes, SIN: No. Sodium Borate (CAS 1330-43-4): REACH: PR, SVHC: Yes, SIN: No. NOTE: PR (Pre-registered), SVHC (Substance of Very High Concern), SIN (Substitute It Now)

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

- 06/May/2015

Preparation Date

- 21/February/2013

Disclaimer/Statement of Liability

- To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or

consequential damages.
