

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Soothe® XP**
- Product Code** • AB49311; Core No. 493; NDC 24208-490-15 (15 mL); NDC 24208-490-95 (2.5 mL)
- 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** • Use in accordance with product literature. Do not use if solution changes color or becomes cloudy; Remove contact lenses before using

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	%	Classifications According to Regulation/Directive
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Edetate Disodium	CAS:6381-92-6	< 0.1%	UN GHS: NDA
Light mineral oil	CAS:8042-47-5 EINECS:232-455-8	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Mineral oil	CAS:8042-47-5 EINECS:232-455-8	< 5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Octoxynol-40	CAS:9004-87-9	< 1%	UN GHS: NDA
Polyquaternium-1	CAS:75345-27-6	0.0013%	UN GHS: NDA
Polysorbate 80	CAS:9005-65-6	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 90%	UN GHS: NDA
Sodium Borate	CAS:1330-43-4 EINECS:215-540-4	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; STOT SE 2

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.

Incompatible Materials or Ignition Sources • None specified.

Specific end use(s)

- Refer to Section 1.2 - Relevant identified uses.

Other Information

- Refer to product literature.

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 British Columbia	Canada Nova Scotia	Canada Ontario	Canada Quebec
Sodium Borate (1330-43-4)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, listed under Borate compounds, inorganic)	1 mg/m3 TWAEV
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, listed under Borate compounds, inorganic)	Not established
Exposure Limits/Guidelines (Con't.)						
	Result	Germany DFG	Germany TRGS	NIOSH		
Sodium Borate (1330-43-4)	TWAs	Not established	Not established	1 mg/m3 TWA		
Boric acid (10043-35-3)	TWAs	Not established	0.5 mg/m3 TWA AGW (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed, exposure factor 2)	Not established		
	Ceilings	10 mg/m3 Peak (inhalable fraction, as B)	Not established	Not established		
	MAKs	10 mg/m3 TWA MAK (inhalable fraction, as B)	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 (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	Milky
Color	White to off-white.	Odor	No odor.
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	7.0-7.8
Specific Gravity/Relative Density	= 1.007	Water Solubility	Soluble
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

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 (< 1%)	1330-43-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Polysorbate 80 (< 1%)	9005-65-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 34500 µL/kg; Irritation: Eye-Rabbit • 150 mg • Mild irritation; Reproductive: Ingestion/Oral-Rat TDLo • 635 g/kg (multigenerations); <i>Reproductive Effects:Effects on Newborn:Viability index (e.g., # alive at day 4 per # born alive); Reproductive Effects:Effects on Newborn:Weaning or lactation index;</i> Tumorigen / Carcinogen: Ingestion/Oral-Rat TDLo • 2163 g/kg 2 Year(s)-Continuous; Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Endocrine:Adrenal cortex tumors
Octoxynol-40 (< 1%)	9004-87-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7900 mg/kg
Mineral oil (< 5%)	8042-47-5	Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 92 g/kg 92 Day(s)-Continuous; Liver:Changes in liver weight; Blood:Changes in leucocyte (WBC) count; Nutritional and Gross Metabolic:Gross Metabolite Changes:Weight loss or decreased weight gain
Purified water (> 90%)	7732-18-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >90 mL/kg

GHS Properties	Classification
Acute toxicity	UN GHS • No data available
Aspiration Hazard	UN GHS • No data available
Carcinogenicity	UN GHS • No data available
Germ Cell Mutagenicity	UN GHS • No data available
Skin corrosion/Irritation	UN GHS • No data available
Skin sensitization	UN GHS • No data available
STOT-RE	UN GHS • No data available

STOT-SE	UN GHS • No data available
Toxicity for Reproduction	UN GHS • No data available
Respiratory sensitization	UN GHS • No data available
Serious eye damage/Irritation	UN GHS • No data available

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		
	CAS	NTP
Polysorbate 80	9005-65-6	Evidence of Carcinogenicity
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

- 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
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 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
Boric acid	10043-35-3	Yes	Yes	Yes
Sodium Borate	1330-43-4	Yes	Yes	Yes
Octoxynol-40	9004-87-9	Yes	No	Yes
Polyquaternium-1	75345-27-6	Yes	No	No
Polysorbate 80	9005-65-6	Yes	No	Yes
Purified water	7732-18-5	Yes	Yes	Yes
Mineral oil	8042-47-5	Yes	Yes	Yes

Canada

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Not Listed
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria

• Boric acid	10043-35-3	D2A
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyquaternium-1	75345-27-6	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	1 %
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	1 %
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Repr.Cat.2; R60-61
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	4.5%≤C: Repr.Cat.2; R:60-61
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	5.5%≤C: Repr.Cat.2; R:60-61
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	T R:60-61 S:53-45
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	S:53-45
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed

• Boric acid	10043-35-3	S:53-45
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

United States - California

Environment

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Not Listed
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Not Listed
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Not Listed
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed

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

• Polysorbate 80	9005-65-6	Not Listed
• Sodium Borate	1330-43-4	Not Listed
• Octoxynol-40	9004-87-9	Not Listed
• Mineral oil	8042-47-5	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyquaternium-1	75345-27-6	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	● 26/December/2013
Preparation Date	● 26/December/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.
