

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Prolensa™ (bromfenac ophthalmic solution) 0.07%**
- Product Code** • AB49405; AB49456; Core No. 494; NDC 24208-602-01 (1.6 mL); NDC 24208-602-03 (3 mL); NDC 24208-602-06 (0.6 mL - Sample)

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

- Recommended use** • A nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.
- Restrictions on use** • Refer to product prescribing information.

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

Label elements

UN GHS

WARNING

- Hazard statements** • May cause eye irritation in sensitive individuals
May cause skin irritation or dryness.
May be harmful if swallowed

Precautionary statements

- Prevention** • Use only in accordance with label instructions and supplied prescribing information.
Wash thoroughly after handling.

- Response**
- If eye irritation persists: Get medical advice/attention.
 - IF ON SKIN: Wash with plenty of soap and water.
 - If skin irritation occurs: Get medical advice/attention.
 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

- Storage/Disposal**
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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
Disodium Edetate	CAS:6381-92-6	< 1%	NDA	UN GHS: NDA	NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 1%	Ingestion/Oral-Rat LD50 • >90 mL/kg	UN GHS: NDA	NDA
Povidone	CAS:9003-39-8	< 1%	Ingestion/Oral-Rat LD50 • 100 g/kg	UN GHS: NDA	NDA
Sodium Borate	CAS:1303-96-4	< 1%	Ingestion/Oral-Rat LD50 • 2660 mg/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2	NDA
Boric acid	CAS:10043-35-3 EINECS:233-139-2	> 1%	Ingestion/Oral-Rat LD50 • 2660 mg/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1	NDA
Sodium sulfite	CAS:7757-83-7 EINECS:231-821-4	< 1%	Ingestion/Oral-Rat LD50 • 3560 mg/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Resp. Sens. 1; Skin Sens. 1; Acute Tox. Oral 5	NDA
Bromfenac Sodium Sesquihydrate	CAS:120638-55-3	0.07%	NDA	UN GHS: NDA	NDA
Benzalkonium Chloride	CAS:68391-01-5 EINECS:269-919-4	0.005%	NDA	UN GHS: NDA	NDA
Tyloxapol	CAS:25301-02-4	< 1%	Ingestion/Oral-Rat LD50 • >5 g/kg	UN GHS: Skin Irrit. 2; Eye Irrit. 2A	NDA

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**
- Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.
- 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

- Notes to Physician**
- The safety of this product in children has not been established. Pregnancy: The safety of this product in pregnant women has not been established. Nursing Mothers: The safety of this product in nursing mothers has not been established.

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**
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up

Measures 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	Germany DFG	NIOSH
Sodium Borate (1303-96-4)	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	5 mg/m3 TWA
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
	Ceilings	Not established	10 mg/m3 Peak (inhalable fraction, as B)	Not established
	MAKs	Not established	10 mg/m3 TWA MAK (inhalable fraction, as B)	Not established

Exposure Control Notations**ACGIH**

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

Exposure Limits Supplemental**ACGIH**

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

Other Information

- Use only in accordance with product literature. KEEP OUT OF REACH OF CHILDREN.

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

Material Description			
Physical Form	Liquid	Color	Colorless to slightly yellow.
General Properties			
Boiling Point	Not determined	Decomposition Temperature	Not determined
pH	7.8	Specific Gravity/Relative Density	1.0
Water Solubility	Soluble		
Flammability			
Flash Point	Not relevant	Flammability (solid, gas)	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		
Water (> 1%)	7732-18-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >90 mL/kg
Povidone (< 1%)	9003-39-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 100 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i>
Sodium Borate (< 1%)	1303-96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Boric acid (> 1%)	10043-35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Sodium sulfite (< 1%)	7757-83-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3560 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Behavioral:Convulsions or effect on seizure threshold; Skin and Appendages:Other:Hair</i>
Tyloxapol (< 1%)	25301-02-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • >5 g/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 • 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

Medical Conditions Aggravated by Exposure Potential Health Effects

- Long Term Exposure: Avoid unnecessary exposure. pre-existing liver or gastrointestinal conditions may be aggravated.

Inhalation**Acute (Immediate)**

- No hazard when used as directed.

Chronic (Delayed)

- No data available

Skin**Acute (Immediate)**

- May cause mild irritation.

Chronic (Delayed)

- No data available

Eye**Acute (Immediate)**

- May cause eye irritation in sensitive individuals.

Chronic (Delayed)

- No data available

Ingestion**Acute (Immediate)**

- Gastric exposure of large doses has been associated with ulceration and necrosis of gastrointestinal structures, as well as severe liver damage. Ingestion of large doses may cause central nervous system effects, including drowsiness, dizziness, and vision disorders. Effects of ingestion of lower doses, as present in the ophthalmic solution, are unknown. Avoid unnecessary exposure.

Chronic (Delayed)

- Chronic ingestion of larger doses can cause severe liver damage. Chronic oral exposure of large doses may be associated with gastrointestinal disturbances, such as nausea, vomiting, heartburn and epigastric pain. Central nervous system effects may include drowsiness, dizziness, and vision disorders.

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
Sodium sulfite	7757-83-7	Group 3-Not Classifiable	Not Listed

Other information

- Bromfenac Sodium (CAS# 120638-55-3) is known to cause liver damage in humans who have taken this potent pain reliever orally in recommended doses (significantly larger than the quantities used in optical solutions) for periods extending beyond the recommended 10 day maximum usage period. Target Organs: Liver, gastrointestinal system and central nervous system.

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	EU EINECS	TSCA
Povidone	9003-39-8	No	Yes
Disodium Edetate	6381-92-6	No	No
Sodium Borate	1303-96-4	No	Yes
Boric acid	10043-35-3	Yes	Yes
Bromfenac Sodium Sesquihydrate	120638-55-3	No	No
Benzalkonium Chloride	68391-01-5	Yes	Yes
Tyloxapol	25301-02-4	No	No
Sodium sulfite	7757-83-7	Yes	Yes
Water	7732-18-5	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Sodium Borate

1303-96-4 D2B

• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Uncontrolled product according to WHMIS classification criteria
• Disodium Edetate	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Boric acid	10043-35-3	D2A
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Povidone	9003-39-8	Uncontrolled product according to WHMIS classification criteria
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Sodium Borate	1303-96-4	1 %
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	1 %
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

Europe

Other

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

• Sodium Borate	1303-96-4	Repr.Cat.2; R60-61
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

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

• Sodium Borate	1303-96-4	8.5%≤C: Repr.Cat.2; R60-61
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	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
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

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

• Sodium Borate	1303-96-4	T R:60-61 S:53-45
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• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	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
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

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

• Sodium Borate	1303-96-4	S:53-45
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	S:53-45
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

United States - California

Environment

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

• Sodium Borate	1303-96-4	Not Listed
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed

• Bromfenac Sodium Sesquihydrate	120638-55-3	Not Listed
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U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Sodium Borate	1303-96-4	Not Listed
• Benzalkonium Chloride	68391-01-5	Not Listed
• Sodium sulfite	7757-83-7	Not Listed
• Disodium Edetate	6381-92-6	Not Listed
• Boric acid	10043-35-3	Not Listed
• Tyloxapol	25301-02-4	Not Listed
• Water	7732-18-5	Not Listed
• Povidone	9003-39-8	Not Listed
• Bromfenac Sodium Sesquihydrate	120638-55-3	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

- 04/April/2013

Preparation Date

- 04/April/2013

Disclaimer/Statement of Liability

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