Safety Data Sheet

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Section 1: Identification

Product identifier

Product Name • **Sodium Chloride Hypertonicity 5% Ophthalmic Solution - Private Label**

Product Code • AK15611, FY15611

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

Recommended use • Finshed Pharmaceutical Product; Temporary relief of corneal edema

Restrictions on use • Use in accordance with product literature.

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 - Infotrac

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

Label elements

UN GHS

WARNING

Hazard statements • May cause eye irritation

Precautionary statements

Prevention • Use personal protective equipment as required.
Wash thoroughly after handling.

Response • 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.

Storage/Disposal • Keep tightly closed. Store at room temperature 15-25ºC (59-77ºF), to maintain product

integrity. Use before date marked on carton and/or container.

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	1.067%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Hypromellose (2910)	**CAS:**9004-65-3	2%	**UN GHS:** NDA
Methylparaben	**CAS:**99-76-3 **EINECS:**202-785-7	0.023%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A
Propylene Glycol	**CAS:**57-55-6 **EINECS:**200-338-0	0.114%	**UN GHS:** Skin Irrit. 3; Eye Irrit. 2B
Propylparaben	**CAS:**94-13-3 **EINECS:**202-307-7	0.01%	**UN GHS:** NDA
Sodium Borate	**CAS:**1303-96-4	0.211%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 2
Sodium chloride	**CAS:**7647-14-5 **EINECS:**231-598-3	5%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	**CAS:**7732-18-5 **EINECS:**231-791-2	Balance	**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

- 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

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention if eye irritation persists.

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 15-25ºC (59-77ºF), 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 (1303-96-4)	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m3 TWAEV	5 mg/m3 TWA
	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

- 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 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

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- Gloves are not required under normal handling conditions.

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 slightly yellow.
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	= 1.0463	Water Solubility	Miscible
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	No data available		

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

Other Material Information

- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Sodium chloride (5%)	7647-14-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 3000 mg/kg
Propylene Glycol (0.114%)	57-55-6	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 20 g/kg
Sodium Borate (0.211%)	1303-96-4	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2660 mg/kg
Boric acid (1.067%)	10043-35-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2500 mg/kg; *Behavioral*:**Convulsions or effect on seizure threshold**; *Behavioral*:**Ataxia**
Hypromellose (2910) (2%)	9004-65-3	**Acute Toxicity:** Ingestion/Oral-Mammal LD50 • >10000 mg/kg
Methylparaben (0.023%)	99-76-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2100 mg/kg
Propylparaben (0.01%)	94-13-3	**Acute Toxicity:** Ingestion/Oral-Mouse LD50 • 6332 mg/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)
- 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)
- Causes mild eye irritation.

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

Ingestion

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

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

Other

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

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

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
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
Methylparaben	99-76-3	Yes	Yes	Yes
Propylparaben	94-13-3	Yes	Yes	Yes
Sodium Borate	1303-96-4	Yes	No	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Hypromellose (2910)	9004-65-3	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

• Sodium Borate	1303-96-4	D2B
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Uncontrolled product according to WHMIS classification criteria
• Propylene Glycol	57-55-6	Uncontrolled product according to WHMIS

		classification criteria
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Boric acid	10043-35-3	D2A
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Sodium Borate	1303-96-4	1 %
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	1 %
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	1 %
• 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
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Repr.Cat.2; R60-61
• 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
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	5.5%<=C: Repr.Cat.2; R:60-61
• 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
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	T R:60-61 S:53-45
• 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
• Methylparaben	99-76-3	Not Listed

• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	S:53-45
• Water	7732-18-5	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Sodium Borate	1303-96-4	Not Listed
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

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

• Sodium Borate	1303-96-4	Not Listed
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed
• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium Borate	1303-96-4	Not Listed

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Hypromellose (2910)	9004-65-3	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date
- 27/Oct/2020

Preparation Date
- 07/May/2015

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