5/21/2024: File reviewed, more current MSDS/SDS not available. CAS

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Sensitive Eyes® Plus Saline Solution

Product Code • 620238; 620280; 620300; 620304; 6208410; 6208890; 630202; FCP-4082

Product Description
 Ophthalmic solution for eyes.

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

Recommended use

• Sensitive Eyes Plus Saline Solution is a sterile, preserved solution for rinsing after

cleaning and before lens insertion with heat (thermal), chemical (not heat) and hydrogen peroxide systems; heat disinfection; dilution of enzyme tablets and storage

of soft contact lenses, as recommended by your eye care practitioner.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and

contraindications.

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

• +1 352-323-3500 - International - 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 • Skin Mild Irritation 3

Label elements

UN GHS

WARNING

Hazard statements · Causes mild skin irritation

Precautionary statements

Preparation Date: 03/February/2015

Revision Date: 06/April/2016

Page 1 of 10

Format: GHS Language: English (US)

UN GHS

Response • If skin irritation occurs: Get medical advice/attention.

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	
Boric acid	CAS:10043-35-3 EINECS:233-139-2	1% TO 1.5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1	
Edetate disodium	CAS:6381-92-6	0.025%	UN GHS: not classified	
Polyaminopropyl biguanide	CAS:27083-27-8	0.00003%	UN GHS: not classified	
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	
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 95%	UN GHS: not classified	
Sodium borate	CAS:1303-96-4	< 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

Get medical attention if symptoms occur. 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 ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical

advice/attention.

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.

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

Preparation Date: 03/February/2015 Revision Date: 06/April/2016

Skin

Eye

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

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 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.

Preparation Date: 03/February/2015 Format: GHS Language: English (US) Revision Date: 06/April/2016 **UN GHS** Page 3 of 10

Exposure Limits/Guidelines					
Result ACGIH Canada Quebec		NIOSH			
Sodium borate	TWAs	2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)	5 mg/m3 TWAEV	5 mg/m3 TWA	
(1303-96-4)		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

- •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	General Properties				
Boiling Point Not relevant Melting Point/Freezing Point Not relevant					
Decomposition Temperature Not relevant pH 7.1 to 7.5					
Specific Gravity/Relative Density	= 1.008 Water=1	Water Solubility	Not relevant		
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Preparation Date: 03/February/2015 Format: GHS Language: English (US) Revision Date: 06/April/2016 **UN GHS**

Viscosity	No data available	I	l i			
Volatility	Volatility					
Vapor Pressure	Not relevant	Vapor Density	Not relevant			
Evaporation Rate	No data available					
Flammability	Flammability					
Flash Point	Not relevant	UEL	Not relevant			
LEL	Not relevant	Autoignition	Not relevant			
Environmental						
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% TO 1.5%)	10043- 35-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; Behavioral:Convulsions or effect on seizure threshold; Behavioral:Ataxia; Reproductive: Ingestion/Oral-Rat TDLo • 1600 mg/kg (6-9D preg); Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system; Ingestion/Oral-Rat TDLo • 76 mg/kg (20D preg); Reproductive Effects:Effects on Embryo or Fetus:Fetotoxicity (except death, e.g., stunted fetus)			
Sodium borate (< 1%)	1303- 96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 70 g/kg (90D male); Reproductive Effects:Paternal Effects:Testes, epididymis, sperm duct; Ingestion/Oral-Rat TDLo • 70 g/kg (90D pre); Reproductive Effects:Maternal Effects:Ovaries, fallopian tubes; Ingestion/Oral-Rat TDLo • 37 g/kg (multigenerations); Reproductive Effects:Effects on Newborn:Weaning or lactation index			
Sodium chloride (< 1%)	7647- 14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Ingestion/Oral-Rat TDLo • 1 mg/kg 24 Hour(s); Biochemical:Metabolism (intermediary):Effect on Na-K pump			
Potassium chloride (< 1%)	7447- 40-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2600 mg/kg; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation			

GHS Properties CI	lassification
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Acute toxicity	UN GHS • Acute Toxicity - Classification criteria not met	
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3	
Serious eye damage/Irritation	UN GHS • Classification criteria not met	
Skin sensitization	UN GHS • Classification criteria not met	
Respiratory sensitization	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	
Toxicity for Reproduction	UN GHS • Classification criteria not met	
STOT-SE	UN GHS • Classification criteria not met	
STOT-RE	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)

May cause mild irritation.

Chronic (Delayed)

Causes mild skin irritation.

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

Preparation Date: 03/February/2015 Revision Date: 06/April/2016 **UN GHS** Page 6 of 10

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
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 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	
Polyaminopropyl biguanide	27083-27-8	Yes	No	Yes	
Edetate disodium	6381-92-6	Yes	No	No	
Sodium borate	1303-96-4	Yes	No	Yes	
Boric acid	10043-35-3	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

Canada - WHMIS - Classifications of Substances

 Sodium borate 1303-96-4 D2B

> Uncontrolled product according to WHMIS

· Potassium chloride 7447-40-7 classification criteria (including

23.8%)

Preparation Date: 03/February/2015

Revision Date: 06/April/2016 Page 7 of 10

Edetate disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria Uncontrolled product
Sodium chloride	7647-14-5	according to WHMIS classification criteria
Boric acid	10043-35-3	D2A
Polyaminopropyl biguanide	27083-27-8	Not Listed
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
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	1 %
Polyaminopropyl biguanide	27083-27-8	Not Listed
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
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	Repr.Cat.2; R60-61
Polyaminopropyl biguanide	27083-27-8	Not Listed
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
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	5.5%<=C: Repr.Cat.2; R:60-61
Polyaminopropyl biguanide	27083-27-8	Not Listed
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
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	T R:60-61 S:53-45
Polyaminopropyl biguanide	27083-27-8	Not Listed
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
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed

Preparation Date: 03/February/2015 Revision Date: 06/April/2016 Format: GHS Language: English (US) UN GHS

Boric acid	10043-35-3	S:53-45
Polyaminopropyl biguanide	27083-27-8	Not Listed
Purified water	7732-18-5	Not Listed

United States - California

Sodium borate	1303-96-4	Not Listed
Potassium chloride	7447-40-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	Not Listed
Polyaminopropyl biguanide	27083-27-8	Not Listed
• Purified water	7732-18-5	Not Listed
J.S California - Proposition 65 - Developmental Toxicity		
Sodium borate	1303-96-4	Not Listed
Potassium chloride	7447-40-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	Not Listed
Polyaminopropyl biguanide	27083-27-8	Not Listed
Purified water	7732-18-5	Not Listed
J.S California - Proposition 65 - Reproductive Toxicity - Female		
Sodium borate	1303-96-4	Not Listed
Potassium chloride	7447-40-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	Not Listed
Polyaminopropyl biguanide	27083-27-8	Not Listed
Purified water	7732-18-5	Not Listed
J.S California - Proposition 65 - Reproductive Toxicity - Male		
Sodium borate	1303-96-4	Not Listed
Potassium chloride	7447-40-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Boric acid	10043-35-3	Not Listed
Polyaminopropyl biguanide	27083-27-8	Not Listed
Purified water	7732-18-5	Not Listed

Section 16 - Other Information

Revision Date Last Revision Date Preparation Date

- 06/April/2016
- 06/February/2015
- 03/February/2015

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Preparation Date: 03/February/2015 Revision Date: 06/April/2016 Format: GHS Language: English (US)
UN GHS

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Preparation Date: 03/February/2015 Revision Date: 06/April/2016