Safety Data Sheet

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Section 1: Identification

Product identifier

Product Name • **BIOTRUE™ multi-purpose solution**

Chemical Name • Use only in accordance with label instructions and supplied prescribing information.

Product Code • 623580; 623582; 623586; 623588; FCP-4278

Product Description • Contact Lens Solution.

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

Recommended use • Biotrue multi-purpose solution dissolves protein and cleans, loosens and removes accumulations of film, debris and deposits from soft contact lenses. Biotrue multi-purpose solution helps prevent the formation of irritating deposits on the lens surface. It kills harmful microorganisms on the lens. While your lens is soaking, the formula envelops the lens in a moisture-rich cushion to help the lens remain comfortable throughout the day. Biotrue multi-purpose solution can also be used to rinse lenses.

Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb, Inc

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

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

Precautionary statements

Storage/Disposal • Keep tightly closed. Store at room temperature 15-30ºC (59-86ºF), to maintain product integrity. use before expiration 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%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1
Edetate disodium	**CAS:**6381-92-6	< 0.1%	**UN GHS:** not classified
Poloxamine	**CAS:**26316-40-5	< 5%	**UN GHS:** not classified
Polyaminopropyl biguanide hydrochloride	**CAS:**32289-58-0	0.00013%	**UN GHS:** not classified
Polyquaternium-1 (40%)	**CAS:**68518-54-7	0.0001%	**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
Sodium hyaluronate	**CAS:**9067-32-7	< 0.1%	**UN GHS:** not classified
Sulfobetaine	**CAS:**15163-36-7	< 0.1%	**UN GHS:** not classified
Water	**CAS:**7732-18-5 **EINECS:**231-791-2	> 96%	**UN GHS:** not classified

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

- No specific treatment is necessary since this material is not irritating to the eye.

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 15-30ºC (59-86ºF), to maintain product integrity. use before expiration 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,	Not established	Not established

		inorganic)		
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
- No eye protection is required during normal handling.

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	Clear Colorless to pale yellow.
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	7.3 to 7.7
Specific Gravity/Relative Density	= 1.01	Water Solubility	Not relevant
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Ignition Distance	Not relevant
Autoignition	Not relevant	Flammability (solid, gas)	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

Other Material Information

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

Components		
Boric acid (< 1%)	10043-35-3	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 2500 mg/kg; *Behavioral*:**Convulsions or effect on seizure threshold**; *Behavioral*:**Ataxia**; **Irritation:** Skin-Human • 15 mg 3 Day(s)-Intermittent • Mild irritation; **Reproductive:** Ingestion/Oral-Rat TDLo • 45 g/kg (90D male); *Reproductive Effects:Paternal Effects*:**Testes, epididymis, sperm duct**; 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**
Sodium hyaluronate (< 0.1%)	9067-32-7	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • >800 mg/kg; *Nutritional and Gross Metabolic:Changes in Chemistry or Temperature*:**Other changes**
Sodium chloride (< 1%)	7647-14-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 3000 mg/kg; **Irritation:** Eye-Rabbit • 10 mg • Moderate irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation

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)
- 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)
- 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	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	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**
Edetate disodium	6381-92-6	Yes	No	No
Sodium borate	1303-96-4	Yes	No	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Poloxamine	26316-40-5	Yes	No	Yes
Sodium hyaluronate	9067-32-7	Yes	No	No
Sulfobetaine	15163-36-7	No	No	No
Polyaminopropyl biguanide hydrochloride	32289-58-0	Yes	No	No
Polyquaternium-1 (40%)	68518-54-7	No	No	No
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
• Poloxamine	26316-40-5	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
• Boric acid	10043-35-3	D2A
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Sodium borate	1303-96-4	1 %
• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	1 %
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

Europe

Other

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

• Sodium borate	1303-96-4	Repr.Cat.2; R60-61
• Poloxamine	26316-40-5	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
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	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
• Poloxamine	26316-40-5	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
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

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

• Sodium borate	1303-96-4	T R:60-61 S:53-45
• Poloxamine	26316-40-5	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
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

United States

Environment

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

• Sodium borate	1303-96-4	Not Listed
• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

United States - California

Environment

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

• Sodium borate	1303-96-4	Not Listed
• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

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

• Sodium borate	1303-96-4	Not Listed

• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Poloxamine	26316-40-5	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Sulfobetaine	15163-36-7	Not Listed
• Polyaminopropyl biguanide hydrochloride	32289-58-0	Not Listed
• Sodium hyaluronate	9067-32-7	Not Listed
• Water	7732-18-5	Not Listed
• Polyquaternium-1 (40%)	68518-54-7	Not Listed

Section 16 - Other Information

Last Revision Date
- 12/February/2015

Preparation Date
- 12/February/2015

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