



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Re Nu Advanced Formula**
- Product Code** • 623954; 623955; 624301; 624303; 624305; FCP-4360
- Product Description** • Contact Lens Solution.

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

- Recommended use** • A sterile, borate buffered multi-purpose lens care solution developed for cleaning, rinsing, protein removal, disinfecting and storage of soft contact lenses, including silicone hydrogel lenses.
- 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

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

- OSHA HCS 2012** • Classification criteria not met

Label elements

OSHA HCS 2012

Classification criteria not met

Other hazards

- OSHA HCS 2012** • Classification criteria not met.

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	%
Boric acid	CAS:10043-35-3 EINECS:233-139-2	< 1%
Sodium borate	CAS:1303-96-4 EU Index:005-011-01-1	< 1%
Edetate disodium	CAS:6381-92-6	< 1%
Poloxamine	CAS:11111-34-5	< 5%
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 0.1%
Purified water	CAS:7732-18-5 EINECS:231-791-2	> 95%
Sodium citrate	CAS:6132-04-3	< 1%
Glycylglycine	CAS:556-50-3 EINECS:209-127-8	< 1%
Poloxamer 181	CAS:9003-11-6 EU Index:618-355-0	< 0.1%
Polyquaternium-1	CAS:75345-27-6	0.00015%
Alexidine dihydrochloride	CAS:22573-93-9 EINECS:245-096-7	0.0002%
Polyaminopropyl biguanide	CAS:32289-58-0 EU Index:616-207-00-X	0.00005%

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

- 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 15-30°C (59-86°F), 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 Ontario	Canada Quebec	NIOSH

Sodium borate (1303-96-4)	STELs	6 mg/m3 STEL (inhalable particulate matter, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable particulate matter, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, listed under Borate compounds, inorganic)	5 mg/m3 TWAEV	5 mg/m3 TWA
Boric acid (10043-35-3)	STELs	6 mg/m3 STEL (inhalable particulate matter, listed under Borate compounds, inorganic)	6 mg/m3 STEL (inhalable, listed under Borate compounds, inorganic)	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable particulate matter, listed under Borate compounds, inorganic)	2 mg/m3 TWA (inhalable, 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.	Odor Threshold	Not relevant
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing Point	Not relevant
Decomposition Temperature	Not relevant	pH	7.5 to 7.9 @ 21 °C(69.8 °F)

Specific Gravity/Relative Density	= 1.009 Water=1	Water Solubility	Soluble
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	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 • 2660 mg/kg
Sodium borate (< 1%)	1303-96-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2660 mg/kg
Edetate disodium (< 1%)	6381-92-6	Mutagen: Cytogenetic analysis • Unreported Route-Hamster • Lung (Somatic cell) • 200 mg/L
Sodium chloride (< 0.1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg
Sodium citrate (< 1%)	6132-04-3	Acute Toxicity: In Vitro IC50 • 22 mmol/L 24 Hour(s)
Poloxamer 181 (< 0.1%)	9003-11-6	Acute Toxicity: Ingestion/Oral-Mouse LD50 • >15 g/kg

Polyquaternium-1 (0.00015%)	75345-27-6	Mutagen: DNA damage • Human • Other Cell Type • 0.01 pph 15 Minute(s) 15 Minute(s)
Polyaminopropyl biguanide (0.00005%)	32289-58-0	Multi-dose Toxicity: Skin-Mouse TDLo • 420 g/kg 80 Week(s)-Intermittent; <i>Liver:Tumors</i> ; <i>Nutritional and Gross Metabolic:Gross Metabolite Changes:Weight loss or decreased weight gain</i>

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012 • Classification criteria not met
Skin corrosion/Irritation	OSHA HCS 2012 • Classification criteria not met
Serious eye damage/Irritation	OSHA HCS 2012 • Classification criteria not met
Skin sensitization	OSHA HCS 2012 • Classification criteria not met
Respiratory sensitization	OSHA HCS 2012 • Classification criteria not met
Aspiration Hazard	OSHA HCS 2012 • Classification criteria not met
Carcinogenicity	OSHA HCS 2012 • Classification criteria not met
Germ Cell Mutagenicity	OSHA HCS 2012 • Classification criteria not met
Toxicity for Reproduction	OSHA HCS 2012 • Classification criteria not met
STOT-SE	OSHA HCS 2012 • Classification criteria not met
STOT-RE	OSHA HCS 2012 • 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	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	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
Alexidine dihydrochloride	22573-93-9	No	Yes	No
Sodium borate	1303-96-4	Yes	No	Yes
Boric acid	10043-35-3	Yes	Yes	Yes
Purified water	7732-18-5	Yes	Yes	Yes
Glycylglycine	556-50-3	Yes	Yes	Yes
Poloxamine	11111-34-5	Yes	No	Yes
Poloxamer 181	9003-11-6	Yes	No	Yes

Polyaminopropyl biguanide	32289-58-0	Yes	No	No
Polyquaternium-1	75345-27-6	Yes	No	No
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium citrate	6132-04-3	No	No	No

Canada

Labor

Canada - WHMIS 1988 - Classifications of Substances

• Sodium borate	1303-96-4	D2B
• Sodium citrate	6132-04-3	Uncontrolled product according to WHMIS classification criteria
• 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
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

Canada - WHMIS 1988 - Ingredient Disclosure List

• Sodium borate	1303-96-4	1 %
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	1 %
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

Europe

Other

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

• Sodium borate	1303-96-4	Repr.Cat.2; R60-61
• Sodium citrate	6132-04-3	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
• Glycylglycine	556-50-3	Not Listed

• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Carc.Cat.3; R40 Xn; R22 T; R48/23 Xi; R41 R43 N; R50-53
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	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
• Sodium citrate	6132-04-3	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
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

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

• Sodium borate	1303-96-4	T R:60-61 S:53-45
• Sodium citrate	6132-04-3	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
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	T N R:22-40-41-43-48/23-50/53 S:(1/2)-22-36/37/39-45-60-61
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

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

• Sodium borate	1303-96-4	S:53-45
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	S:53-45
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	S:(1/2)-22-36/37/39-45-60-61
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern for Authorisation

• Sodium borate	1303-96-4	Reason for inclusion Toxic for reproduction, Article 57c (603-
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		411-9)
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Reason for inclusion Toxic for reproduction, Article 57c (233-139-2)
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

United States

Environment

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

• Sodium borate	1303-96-4	Not Listed
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

United States - California

Environment

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

• Sodium borate	1303-96-4	Not Listed
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

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

• Sodium borate	1303-96-4	Not Listed
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed

• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• Sodium borate	1303-96-4	Not Listed
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• Sodium borate	1303-96-4	Not Listed
• Sodium citrate	6132-04-3	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Boric acid	10043-35-3	Not Listed
• Glycylglycine	556-50-3	Not Listed
• Poloxamine	11111-34-5	Not Listed
• Purified water	7732-18-5	Not Listed
• Polyaminopropyl biguanide	32289-58-0	Not Listed
• Poloxamer 181	9003-11-6	Not Listed
• Polyquaternium-1	75345-27-6	Not Listed
• Alexidine dihydrochloride	22573-93-9	Not Listed

Section 16 - Other Information

Revision Date	• 26/January/2017
Last Revision Date	• 26/January/2017
Preparation Date	• 26/January/2017
Disclaimer/Statement of Liability	<ul style="list-style-type: none"> 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.