



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Amvisc/Amvisc Plus**

Product Code

- 59081/59081L (Amvisc); 60081/60081L (Amvisc Plus)

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

Recommended use

- Finished Pharmaceutical Product; Amvisc/Amvisc Plus is indicated for use as a surgical aid in ophthalmic anterior and posterior segment procedures.

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

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

- Classification criteria not met

Label elements

UN GHS**Precautionary statements**

- Storage/Disposal** • Keep tightly closed and store in upright position.
Store product refrigerated at 2-8°C (36-46°F).
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
Sodium hyaluronate	CAS:9004-61-9 EINECS:232-678-0	1.2% TO 1.6%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Sodium phosphate, dibasic, heptahydrate	CAS:7782-85-6	< 0.1%	UN GHS: NDA
Sodium phosphate monobasic, monohydrate	CAS:10049-21-5	< 0.1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

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 between 2-8°C (36-46°F), to maintain product integrity. use before expiration date marked on carton and/or container. Protect from freezing.

Section 8 - Exposure Controls/Personal Protection

Control parameters**Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls**Engineering Measures/Controls**

- No data available

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	Appearance/Description	Colorless, transparent viscous liquid.
Color	Colorless	Odor	No odor.
Odor Threshold	Not relevant	Physical and Chemical Properties	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6.8 to 7.6 No data available
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available	Volatiles (Wt.)	Not relevant
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available	Degradation	Not relevant

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable when stored refrigerated at 2-8C (36-46 F). Use before expiration date marked on carton and/or container.

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 (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg
Sodium phosphate, dibasic, heptahydrate (< 0.1%)	7782-85-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 12930 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)**
 - 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.

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
Sodium hyaluronate	9004-61-9	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium phosphate, dibasic, heptahydrate	7782-85-6	No	No	No
Sodium phosphate monobasic, monohydrate	10049-21-5	No	No	No
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

Uncontrolled product

• Sodium chloride	7647-14-5	according to WHMIS classification criteria
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

United States

Environment

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

• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

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

• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Not Listed

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

• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Sodium phosphate, dibasic, heptahydrate	7782-85-6	Not Listed
• Sodium hyaluronate	9004-61-9	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date • 14/May/2015

Preparation Date

- 06/May/2015

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