



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Brimonidine Tartrate Ophthalmic Solution, 0.2%**

Product Code

- AB41107; AB41109; AB41111; Core No. 411; NDC 24208-0411-05; NDC 24208-0411-10; NDC 24208-0411-15

Product Description

- Ophthalmic solution for eyes.

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

Recommended use

- Finished Pharmaceutical Product; Brimonidine tartrate ophthalmic solution 0.2% is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

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

- 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 15-25°C (59-77°F), 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
Benzalkonium Chloride	CAS:63449-41-2 EINECS:264-151-6	0.005%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Brimonidine L-tartrate	CAS:70359-46-5	0.2%	UN GHS: NDA
Citric acid, monohydrate	CAS:5949-29-1	< 0.1%	UN GHS: NDA
Polyvinyl alcohol	CAS:9002-89-5	1% TO 5%	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 Citrate Dihydrate	CAS:68-04-2 EINECS:200-675-3	< 1%	UN GHS: Eye Irrit. 2A
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

- 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 15-25°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.

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	Clear Greenish 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	= 1.01	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	Flame Height	Not relevant
Autoignition	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored at room temperature 15-25°C (59-77°F). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

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		
Benzalkonium Chloride (0.005%)	63449-41-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg; Behavioral: Somnolence (general depressed activity); Blood: Hemorrhage
Polyvinyl alcohol (1% TO 5%)	9002-89-5	Acute Toxicity: Ingestion/Oral-Mouse LD50 • >4000 mg/kg
Sodium Citrate Dihydrate (< 1%)	68-04-2	Acute Toxicity: Intraperitoneal-Rat LD50 • 1548 mg/kg; Behavioral: Convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: Cyanosis; Gastrointestinal: Changes in structure or function of salivary glands
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg
Citric acid, monohydrate (< 0.1%)	5949-29-1	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 5790 mg/kg; Behavioral: Ataxia; Cardiac: Change in rate; Lungs, Thorax, or Respiration: Respiratory depression

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 • Eye Mild Irritation 2B

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)**

- May cause eye irritation in sensitive individuals. Ocular effects including: oral dryness, ocular hyperemia, burning and stinging, blurring, foreign body sensation, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Ingestion**Acute (Immediate)**

- Small amounts (less than a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.

Chronic (Delayed)

- No data available

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	IARC	NTP
Polyvinyl alcohol	9002-89-5	Group 3-Not Classifiable	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
Benzalkonium Chloride	63449-41-2	Yes	Yes	Yes
Brimonidine L-tartrate	70359-46-5	No	No	No
Citric acid, monohydrate	5949-29-1	Yes	No	No
Polyvinyl alcohol	9002-89-5	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium Citrate Dihydrate	68-04-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Citric acid, monohydrate	5949-29-1	E
• Sodium Citrate Dihydrate	68-04-2	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

Europe

Other

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed

• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	C N R:21/22-34-50 S:(2)-36/37/39-45-61
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	S:(2)-36/37/39-45-61
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

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

• Citric acid, monohydrate	5949-29-1	Not Listed
• Sodium Citrate Dihydrate	68-04-2	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Brimonidine L-tartrate	70359-46-5	Not Listed

Section 16 - Other Information**Last Revision Date**

- 15/May/2015

Preparation Date

- 15/May/2015

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