

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

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Core No. 411

### 1. PRODUCT AND COMPANY INFORMATION

**Product Name:** Brimonidine Tartrate Ophthalmic Solution 0.2%  
**Generic Name:** Brimonidine Tartrate Ophthalmic Solution 0.2%  
**NDC No.** 24208-411-05 ( 5 ml)  
24208-411-10 (10 ml)  
24208-411-15 (15 ml)

**Legal Category:** Pharmaceutical preparation, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

**Drug Composition:** Alpha-2 adrenergic agonist

BAUSCH & LOMB PHARMACEUTICALS, INC.

8500 Hidden River Parkway

Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST

Emergency: (800) 227-1427 24 hrs

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	% Content
Brimonidine Tartrate	59803-94-4	NE	NE	0.2
Polyvinyl Alcohol	9002-89-5	NE	NE	≥1
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Sodium Chloride, Sodium Citrate, Citric Acid, Benzalkonium Chloride

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

Presents little or no hazards if spilled and no unusual hazard if involved in fire.

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#### POTENTIAL HEALTH HAZARDS

**Carcinogenicity:** (NTP) No (IARC) No (OSHA) No

No compound-related carcinogenic effects were observed in either mice or rats following a 21-month and 24-month study, respectively. In these studies, dietary administration of brimonidine tartrate at doses up to 2.5 mg/kg/day in mice and 1.0 mg/kg/day in rats achieved ~77 and 118 times, respectively, the plasma drug concentration estimated in humans treated with one drop brimonidine tartrate ophthalmic solution 0.2% into both eyes 3 times per day.

Brimonidine tartrate was not mutagenic or cytogenic in a series of in vitro and in vivo studies including the Ames test, chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, a host-mediated assay and cytogenic studies in mice, and dominant lethal assay.

Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of harm to the fetus due to brimonidine tartrate ophthalmic solution 0.2%.

**Eye:** Brimonidine tartrate ophthalmic solution 0.2% is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The preservative in brimonidine tartrate ophthalmic solution 0.2%, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling brimonidine tartrate ophthalmic solution 0.2% to insert soft contact lenses.

**Skin:** Irritant

**Ingestion:** Harmful if swallowed

**Inhalation:** Harmful if inhaled

**Chronic Effects:** Not known

**Target Organs:** Liver

**Medical Conditions Aggravated by Long Term Exposure:** No information is available on overdosage in humans. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

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#### **4. FIRST AID MEASURES**

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**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

**Note to Physicians:** Although brimonidine tartrate ophthalmic solution 0.2% had minimal effect on blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

Brimonidine tartrate ophthalmic solution 0.2% has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients.

Brimonidine tartrate ophthalmic solution 0.2% should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangiitis obliterans.

During the studies there was a loss of effect in some patients. The IOP-lowering efficacy observed with brimonidine tartrate ophthalmic solution 0.2% during the first month of therapy may not always reflect the long-term level of IOP reduction. Patients prescribed IOP-lowering medication should be routinely monitored for IOP.

**Pregnancy:** Teratogenic Effects: Pregnancy Category B.

Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of harm to the fetus due to brimonidine tartrate ophthalmic solution 0.2%. Dosing at this level produced 100 times the plasma drug concentration level seen in humans following multiple ophthalmic doses.

There are no adequate and well-controlled studies in pregnant women. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Brimonidine tartrate ophthalmic solution 0.2% should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk; in animal studies brimonidine tartrate was excreted in breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Additional details are available on the package insert or in the [Physicians Desk Reference](#).

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## 5. FIRE FIGHTING MEASURES

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**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** Hydrogen Bromide and Nitrogen Oxides

**Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

**Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

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## 6. ACCIDENTAL RELEASE MEASURES

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**Large/Small Spills:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

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## 7. HANDLING AND STORAGE

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**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

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## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

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**Engineering Controls:** In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and

protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

**Skin Protection:** Thick impermeable gloves and protective clothing.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

**Warning: Do not use air-purifying respirators in oxygen-depleted environments.** No respiratory protection is required in the clinical or home environment.

**Other:** None

**Ventilation:** Recommended

**Contaminated Equipment:** Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

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## 9. CHEMICAL & PHYSICAL PROPERTIES

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Appearance & Odor:	Clear, greenish-yellow color		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

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## 10. STABILITY AND REACTIVITY

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**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:** Hydrogen Bromide and Nitrogen Oxides

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY

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**Summary of Risks:** Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material

CAS# 70359-46-5                      **Brimonidine Tartrate**

May cause irritation to the eyes and skin. May be harmful to the digestive and respiratory tract.

CAS# 77-92-9                              **Citric Acid**

May cause irritation to the eyes and respiratory tract. Mild irritant to the skin. Naturally occurring compound in plant and animal tissues. Generally recognized as safe in foods. Chronic oral over exposure can cause tooth enamel damage. Oral-rat LD<sub>50</sub> 11,700 mg/kg. Severe irritation eye 750 mg/24 hr.

CAS # 9002-89-5                      **Polyvinyl Alcohol**

Dust may cause irritation to eyes and respiratory tract. No known effects by skin contact or ingestion. Inhalation of dust can induce bronchitis or asthma attacks in some individuals. No known dermal effects due to acute exposure. Degradation products of stored material are methanol (PEL=260 mg/M<sup>3</sup>) and methyl acetate (TLV=200 ppm). Decomposition products are acetaldehyde, crotonaldehyde and acetone. Oral-rat LD<sub>50</sub> >10 mg/kg. Acetaldehyde: CAS# 75-07-0; TLV=100 ppm; Suspected Carcinogen. Crotonaldehyde: CAS# 4170-30-3; PEL=2 ppm; Suspected Carcinogen. Acetone: CAS# 67-64-1; TLV= 750 ppm.

CAS # 7647-14-5                      **Sodium Chloride**

May cause irritation to eyes, skin, nerves, respiratory, and digestive tract. Eyes and respiratory tract can be irritated by solid or dust. Prolonged skin contact can cause irritation. Ingestion of large amounts can cause high blood pressure (hypertension) and congestion of the internal organs (esp. the meninges and brain), cramps, vomiting, prostration, coma and death.

CAS # 54-64-8                              **Sodium Citrate Dihydrate**

May cause irritation to eyes, skin, respiratory, and digestive tract. Target organs are the central nervous system, kidneys and bones. Increased risk persons have impaired renal function, dehydration, sodium restricted diets or hypertension. This information may be based on general information regarding sodium salts. Ingestion of large doses can cause nausea, vomiting, convulsions, diarrhea, and hypernoia (hyper mental activity or imagination). Chronic exposure can cause urolithiasis (build-up of calcium deposits in the urinary tract) due to increased extraction of calcium from the bones.

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**12. ECOLOGICAL INFORMATION**

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**Chemical Fate Information:** Product administered to patients presents a negligible impact on the environment.

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**13. DISPOAL INFORMATION**

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**Dispose of material according to Federal, State, and Local regulations.** The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

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**14. TRANSPORTATION INFORMATION**

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**Transportation Data:** Not classified as hazardous by DOT regulations.

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**15. REGULATORY INFORMATION**

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**DOT Designations:** Not classified as hazardous by DOT regulations.

**EPA Designations:** RCRA Hazardous Waste  
(40 CFR 261.33) Not Listed

**FDA Designations:** Prescription only medication.  
NDC No. 24208-411-05 ( 5 ml)  
24208-411-10 (10 ml)  
24208-411-15 (15 ml)

**OSHA Designations:** (29 CFR 1910.1000, Table Z)  
Not Listed

**SARA Title III:** Not listed under Section 313 of Toxic Release Reporting.

**CALIFORNIA PROPOSITION 65:** Not Listed

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**16. OTHER INFORMATION**

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None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper

BAUSCH & LOMB Pharmaceuticals Division  
MSDS: Brimonidine Tartrate Ophthalmic Solution 0.2%

use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than