

## Safety Data Sheet

### Section 1: Identification

#### Product identifier

**Product Name**

- **Carteolol Hydrochloride Ophthalmic Solution, 1%**

**Product Code**

- AB36707; AB36709; Ab36711; Core No. 367; NDC 24208-0367-05; NDC 24208-0367-10; NDC 24208-0367-15

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

**Recommended use**

- Finished Pharmaceutical Product; Carteolol hydrochloride ophthalmic solution USP, 1%, has been shown to be effective in lowering intraocular pressure and may be used in patients with chronic open-angle glaucoma and intraocular 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  
Specific Target Organ Toxicity Single Exposure 1

#### Label elements

**UN GHS**

**DANGER**



**Hazard statements** • May cause eye irritation

May cause damage to organs - Lungs, Heart via Unreported Route  
Suspected of damaging fertility or the unborn child.

### Precautionary statements

**Prevention** ● Do not handle until all safety precautions have been read and understood.  
Wash thoroughly after handling.  
Use personal protective equipment as required.

**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.  
IF ON SKIN: Wash with plenty of soap and water.  
If skin irritation or rash occurs: Get medical advice/attention.  
Specific treatment, see supplemental first aid information.

**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.  
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

### 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 Solution	CAS:139-07-1 EINECS:205-351-5	0.01%	UN GHS: NDA
Carteolol HCl	CAS:51781-21-6 EINECS:257-415-7	1%	UN GHS: NDA
Dibasic Sodium Phosphate	CAS:7558-79-4 EINECS:231-448-7	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Monobasic Sodium Phosphate	CAS:7558-80-7 EINECS:231-449-2	< 0.1%	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
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

The exact percentage of composition has been withheld as a trade secret.

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

- Skin**
- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.
- 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: Get medical advice/attention.
- Ingestion**
- If accidentally ingested, efforts to decrease further absorption may be appropriate (gastric lavage). Call a physician or poison control center.

**Most important symptoms and effects, both acute and delayed**

- As with other topically applied ophthalmic preparations, carteolol may be absorbed systemically. The same adverse reactions found with systemic administration of betaadrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma and rarely death in association with cardiac failure, have been reported with topical application of beta-adrenergic blocking agents.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician**

- The most common signs and symptoms to be expected with overdosage with administration of a systemic beta-adrenergic blocking agent are symptomatic bradycardia, hypotension, bronchospasm, and acute cardiac failure. Should these symptoms occur, discontinue carteolol therapy and initiate appropriate supportive therapy. The following supportive measures should be considered: 1. Symptomatic bradycardia: Use atropine sulfate intravenously in a dosage of 0.25 mg to 2 mg to induce vagal blockade. If bradycardia persists, intravenous isoproterenol hydrochloride should be administered cautiously. In refractory cases the use of a transvenous cardiac pacemaker should be considered. 2. Hypotension: Use sympathomimetic pressor drug therapy, such as dopamine, dobutamine or levarterenol. In refractory cases, the use of glucagon hydrochloride may be useful. 3. Bronchospasm: Use isoproterenol hydrochloride. Additional therapy with aminophylline may be considered. 4. Acute cardiac failure: Conventional therapy with digitalis, diuretics and oxygen should be instituted immediately. In refractory cases the use of intravenous aminophylline is suggested. This may be followed, if necessary, by glucagon hydrochloride which may be useful. 5. Heart block (second or third degree): Use isoproterenol hydrochloride or a transvenous cardiac pacemaker.

**Other information**

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**Section 5: Fire-Fighting Measures**

**Extinguishing media**

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO2, water spray or regular foam.  
LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

**Special hazards arising from the substance or mixture**

- Unusual Fire and Explosion Hazards**
- None known.

- Hazardous Combustion Products**
- None known.

**Advice for firefighters**

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

**Section 6 - Accidental Release Measures**

**Personal precautions, protective equipment and emergency procedures**

### Personal Precautions

- Wear suitable protective eyewear, clothing, respiratory protection, rubber boots and rubber gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

### Emergency Procedures

- Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

### Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

### 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. Dispose of in accordance with Section 13.

## Section 7 - Handling and Storage

### Precautions for safe handling

#### 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.

### 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. Protect from light.

#### Incompatible Materials or Ignition Sources

- None specified.

## 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

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

#### Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

#### Hands

- Wear appropriate gloves.

#### Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

- General Industrial Hygiene Considerations**
- Wash thoroughly after handling.
- 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	Not relevant	Odor Threshold	No data available
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6.2 to 7.2
Specific Gravity/Relative Density	= 1.005 Water=1	Water Solubility	Soluble
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	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

## Section 10: Stability and Reactivity

### Reactivity

- No dangerous reaction known under conditions of normal use.

### 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

- No data available

### Hazardous decomposition products

- No data available

## Section 11 - Toxicological Information

### Information on toxicological effects

Components		
Carteolol HCl (1%)	51781-21-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 1330 mg/kg; <b>Behavioral:</b> Tremor; <b>Behavioral:</b> Ataxia

Benzalkonium Chloride Solution (0.01%)	139-07-1	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 400 mg/kg
Sodium chloride (< 1%)	7647-14-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3000 mg/kg
Monobasic Sodium Phosphate (< 0.1%)	7558-80-7	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 8290 mg/kg
Dibasic Sodium Phosphate (< 0.1%)	7558-79-4	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 17000 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 • Specific Target Organ Toxicity Single Exposure 1
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

**Target Organs**

- Lungs, Heart

**Potential Health Effects**

**Inhalation**

**Acute (Immediate)**

- May cause systemic effects.(See Eye).

**Chronic (Delayed)**

- No data available.

**Skin**

**Acute (Immediate)**

- Not expected to cause skin irritation.

**Chronic (Delayed)**

- Systemic absorption is possible with repeated or prolonged contact.(See Eye).

**Eye**

**Acute (Immediate)**

- Transient ocular burning and stinging. As with other topically applied ophthalmic drugs, carteolol may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported with topical application of beta-adrenergic blocking agents.

**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)**

- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested. May cause systemic effects. (See Eye).

**Chronic (Delayed)**

- No data available.

**Other information**

- TARGET ORGAN: HEART/CARDIOVASCULAR: Bradycardia, arrhythmia, hypotension, syncope, heart block, cerebral vascular accident, cerebral ischemia,

congestive heart failure, palpitation, cardiac arrest. TARGET ORGAN: LUNGS: Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure, dyspnea, nasal congestion.

## 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
Carteolol HCl	51781-21-6	No	Yes	No

Benzalkonium Chloride Solution	139-07-1	Yes	Yes	Yes
Monobasic Sodium Phosphate	7558-80-7	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Dibasic Sodium Phosphate	7558-79-4	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Carteolol HCl	51781-21-6	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Uncontrolled product according to WHMIS classification criteria

## United States

### Environment

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

• Dibasic Sodium Phosphate	7558-79-4	5000 lb final RQ; 2270 kg final RQ
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Carteolol HCl	51781-21-6	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

## United States - California

### Environment

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

• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Carteolol HCl	51781-21-6	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

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

• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Carteolol HCl	51781-21-6	Not Listed



• Monobasic Sodium Phosphate	7558-80-7	Not Listed
------------------------------	-----------	------------

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

• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Carteolol HCl	51781-21-6	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

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

• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Carteolol HCl	51781-21-6	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

**Section 16 - Other Information**

**Last Revision Date**

- 19/May/2015

**Preparation Date**

- 19/May/2015

**Disclaimer/Statement of Liability**

- To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb, Inc. 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, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.