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
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
<th>Classifications According to Regulation/Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium Chloride Solution</td>
<td>CAS:139-07-1</td>
<td>0.01%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:205-351-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carteolol HCI</td>
<td>CAS:51781-21-6</td>
<td>1%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:257-415-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dibasic Sodium Phosphate</td>
<td>CAS:7558-79-4</td>
<td>&lt; 0.1%</td>
<td>UN GHS: Skin Irrit. 2; Eye Irrit. 2A</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-448-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monobasic Sodium Phosphate</td>
<td>CAS:7558-80-7</td>
<td>&lt; 0.1%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-449-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>CAS:7647-14-5</td>
<td>&lt; 1%</td>
<td>UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-598-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>CAS:7732-18-5</td>
<td>Balance</td>
<td>UN GHS: Classification criteria not met</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-791-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Color</th>
<th>Odor</th>
<th>Odor Threshold</th>
<th>pH</th>
<th>Specific Gravity/Relative Density</th>
<th>Water Solubility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liquid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>= 1.005 Water=1</td>
<td>Soluble</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Properties</th>
<th>Boiling Point</th>
<th>Melting Point</th>
<th>pH</th>
<th>Specific Gravity/Relative Density</th>
<th>Water Solubility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6.2 to 7.2</td>
<td>Soluble</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volatility</th>
<th>Vapor Pressure</th>
<th>Vapor Density</th>
<th>Not relevant</th>
<th>Not relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evaporation Rate</td>
<td>Not relevant</td>
<td>Not relevant</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Flash Point</th>
<th>UEL</th>
<th>Autoignition</th>
<th>Not relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
<th>Octanol/Water Partition coefficient</th>
<th>No data available</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity: Ingestion/Oral-Rat LD50 • 1330 mg/kg; Behavioral: Tremor; Behavioral: Ataxia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carteolol HCl (1%)</td>
<td>S1781-21-6</td>
</tr>
</tbody>
</table>
Benzalkonium Chloride Solution (0.01%) | 139-07-1 | **Acute Toxicity**: Ingestion/Oral-Rat LD50 • 400 mg/kg
---|---|---
Sodium chloride (< 1%) | 7647-14-5 | **Acute Toxicity**: Ingestion/Oral-Rat LD50 • 3000 mg/kg
Monobasic Sodium Phosphate (< 0.1%) | 7558-80-7 | **Acute Toxicity**: Ingestion/Oral-Rat LD50 • 8290 mg/kg
Dibasic Sodium Phosphate (< 0.1%) | 7558-79-4 | **Acute Toxicity**: Ingestion/Oral-Rat LD50 • 17000 mg/kg

### GHS Properties

<table>
<thead>
<tr>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
</tr>
<tr>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
</tr>
<tr>
<td>Skin sensitization</td>
</tr>
<tr>
<td>STOT-RE</td>
</tr>
<tr>
<td>STOT-SE</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>DOT</th>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class (es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
</tr>
<tr>
<td>Carteolol HCl</td>
</tr>
</tbody>
</table>
### Canada

#### Labor

**Canada - WHMIS - Classifications of Substances**

- 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 HCI 51781-21-6 Not Listed
- Monobasic Sodium Phosphate 7558-80-7 Not Listed

### 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 HCI 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 HCI 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 HCI 51781-21-6 Not Listed
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>HMIS Code</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobasic Sodium Phosphate</td>
<td>7558-80-7</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### 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.