

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

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Core No. 367

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Carteolol Hydrochloride Ophthalmic Solution USP, 1%
Generic Name: Same
NDC No. 24208-367-05 (5 ml)
24208-367-10 (10 ml)
24208-367-15 (1 5 ml)

Legal Category: Prescription medication, filled in plastic bottles with dropper tips comprised of low density polyethylene, and overpacked inside a cardboard carton.

Drug Composition: Non-selective beta-adrenoceptor blocking agent for ophthalmic use.

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 ³)	PEL(mg/m ³)	% Content
Carteolol hydrochloride	51781-21-6	NE	NE	1.0
Purified Water	7732-18-5	NE	NE	>1

Ingredients <1% - Sodium Chloride, Monobasic and Dibasic Sodium Phosphate, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle with dropper tip in cardboard box. Clear colorless solution. Toxic by ingestion. Presents little or no hazard if spilled and no unusual hazard if involved in fire.

POTENTIAL HEALTH HAZARDS

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

Eye: May cause irritation, burning or stinging on installation. Can cause hypersensitivity (anaphylactic) in some individuals.

Skin: May cause irritation and hypersensitivity in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals.

Inhalation: May cause irritation and hypersensitivity in some individuals. Vapors produced at controlled room temperature are negligible.

Chronic Effects: May cause hypersensitivity. Prolonged use can cause conjunctival injection, watery eyes, itchy eyes, dryness around the eye, puffy eyes, eye irritation and styes. It is unclear if these effects are attributable to the drug.

Target Organs: Eyes.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product.

- Reproduction studies have been performed in rats and mice. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Overdosage: No specific information on emergency treatment of overdosage in humans is available. Should accidental ocular overdosage occur, flush eye(s) with water or normal saline. The most common effects expected with overdosage of a beta-adrenergic blocking agent are bradychardia, bronchospasm, congestive heart failure and hypotension. On the basis of the pharmacologic profile, the following additional measures should be considered as appropriate:

- Symptomatic sinus bradychardia or heart block: Administer atropine. If there is

- no response to vagal blockade, administer isoproterenol cautiously.
- Bronchospasm: Administer a beta₂-stimulating agent such as isoproterenol and/or theophylline derivative.
 - Congestive heart failure: Administer diuretics and digitalis glycosides as necessary.
 - Hypotension: Administer vasopressors such as intravenous dopamine, epinephrine or neopinephrine bitartrate.

Contraindications: Contraindicated in those individuals with bronchial asthma or with a history of bronchial asthma, or severe chronic obstructive pulmonary disease; sinus bradycardia; second or third degree atrioventricular block; overt cardiac failure; cardiogenic shock; or hypersensitivity to any component of this product.

4. FIRST AID MEASURES

Eyes: If not prescribed this medication, 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. Person should tell health personnel if he/she has an ulcer of the G.I. tract. Give plenty of water and bland fluids. If breathing stops, give artificial respiration. 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 immediately.

Note to Physicians: Additional details are available on the package insert or in the Physicians' Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: May emit toxic or irritant fumes when heated.

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.

6. ACCIDENTAL RELEASE MEASURES

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.

7. HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

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. Protect from heat. Wash hands after using.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-25⁰ C (59⁰- 75⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

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 equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Clear, colorless aqueous solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Complete	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Aqueous solutions are stable at ambient room temperature at neutral pH.

Conditions to avoid: Extreme heat or cold.

Incompatibility: N.D..

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

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 #

51781-21-6 **Carteolol Hydrochloride**

There is no evidence of mutagenicity, carcinogenicity, teratogenicity, or impairment of reproduction and fertility in studies investigating potential carteolol preclinical toxicity. When maternally toxic, there is a delayed ossification of fetus' bones. Slight embryoletality at 75 and 150 and equivocal at 3 and 15 mg. More stillborn fetuses in the 3 and 150 mg group (but not in the 30 mg group) F1A pups compared to the 0 group. Fetuses from orally administered mice found to have cleft palates, but it is a statistically insignificant number.

All formulations < 2% in an eye irritation study with rabbits showed evidence of being non-irritating except 2% Carteolol, which was considered non-irritating in females and practically non-irritating in males.

Toxicity:

Oral LD₅₀ (male mouse) = 630 mg/kg Oral LD₅₀ (female rat) = 1330 mg/kg
Oral LD₅₀ (female mouse) = 650 mg/kg Oral LD₅₀ (male rat) = 1380 mg/kg
Intravenous LD₅₀ (male rat) = 158 mg/kg Intravenous LD₅₀ (female rat) = 153 mg/kg.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL INFORMATION

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

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

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. 24208-367-05 (5 ml)
NDC No. 24208-367-10 (10 ml)
NDC No. 24208-367-15 (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

16. OTHER INFORMATION

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

NE- Not Established

< - Less Than

> - Greater Than