



**Dorzolamide Hydrochloride Ophthalmic Solution 2% (Sterile)  
MATERIAL SAFETY DATA SHEET**

Effective Date: 2/27/07

Supersedes: None

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**Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** Dorzolamide Hydrochloride Ophthalmic Solution 2% (Sterile)    **For Information:** 1-800-553-5340  
**Product Code(s):** Core 485    **For Emergency:** 1-800-535-5053  
 NDC 24208-485-05 (5 ml)  
 NDC 24208-485-10 (10 ml)

**Chemical Family:** Carbonic Anhydrase Inhibitor  
**Manufacturer:** Bausch & Lomb, Incorporated  
**Address:** 1400 N. Goodman Street  
 Rochester, New York 14609

**Section 2: COMPOSITION / INFORMATION ON INGREDIENTS**

CAS #	COMPONENT NAME	% W/W	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										UNITS	
			OSHA PEL TWA /STEL	ACGIH TLV TWA /STEL	NIOSH REL TWA /STEL	IRELAND TWA /STEL	HSE TWA /STEL							
130693-82-2	Dorzolamide Hydrochloride	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
6132-04-3	Sodium Citrate Dihydrate, USP	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9004-62-0	Hydroxyethyl Cellulose	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
69-65-8	Mannitol	< 5	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
63449-41-2	Benzalkonium Chloride	0.0075	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water	Bal.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
TOTAL		100***												

N/E: Not Established    OSHA: Occupational Safety & Health Administration    TWA: 8-Hour Time-Weighted Average  
 N/A: Not Applicable    PPM: Parts Per Million    STEL: Short-Term Exposure Limit  
 ACGIH: American Conference of Governmental Industrial Hygienists    C: Ceiling Limit  
 NIOSH: National Institute for Occupational Safety & Health    REL: Recommended Exposure Limit

\* Total Mist  
 \*\* Respirable Mist  
 \*\*\* pH balanced with sodium hydroxide

**Section 3: HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW**

**Caution!! Pharmacologically Active Material. Dorzolamide Hydrochloride Ophthalmic Solution is a carbonic anhydrase inhibitor formulated for topical ophthalmic use. It is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Dorzolamide Hydrochloride Ophthalmic Solution is also a sulfonamide and, although administered topically, it is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration. Do Not Use: if there exists hypersensitivity to any ingredient in this product.**  
**WARNING: Keep out of reach of children.**

**Section 3: HAZARDS IDENTIFICATION (cont.)**

**PRECAUTIONS:**

***Caution! Pharmacologically Active Material***

Dorzolamide Hydrochloride Ophthalmic Solution is a carbonic anhydrase inhibitor formulated for topical ophthalmic use. This product is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Dorzolamide Hydrochloride Ophthalmic Solution is also a sulfonamide and, although administered topically, it is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of Dorzolamide Hydrochloride Ophthalmic Solution.

***Do Not Use:*** if there exists hypersensitivity to any ingredient in this product.

Use only in accordance with product prescribing information.

***WARNING: Keep out of reach of children.***

**POTENTIAL HEALTH EFFECTS**

**EYE:**

In clinical use as a 2% ophthalmic solution, the most frequently reported drug-related ocular side effects and local symptoms were burning/stinging, blurred vision, tearing, dryness, photophobia, eye redness and itching, eyelid inflammation, eye pain, conjunctivitis, and eyelid swelling. The most common adverse, non-ocular drug-related side effects included headache, bitter taste, nausea, dry mouth, asthenia/fatigue and skin rashes. Over exposure may result in acidosis, electrolyte imbalance and central nervous system effects.

**SKIN:**

The 2% ophthalmic solution showed no evidence of sensitization in the guinea pig maximization test (GPMT) and the Buehler test.

**INGESTION:**

May be harmful if swallowed. Electrolyte imbalance, development of an acidotic state, and possible central nervous system effects may occur.

**INHALATION:**

Unlikely to be hazardous when used as directed. Slightly irritating to the respiratory tract.

**CHRONIC HEALTH EFFECTS**

**Dorzolamide Hydrochloride:** Dorzolamide hydrochloride is a potent carbonic anhydrase inhibitor used to reduce elevated intraocular pressure. In repeat-dose studies the following effects were observed: a number of bladder and renal histologic changes in mice and rats; upper gastric tract, metabolic acidosis, bone changes and minor decreases in erythroid parameters in dogs and monkeys. The lowest no-effect level for these changes, most of which were considered secondary to the pharmacological activity of dorzolamide, was 0.05 mg/kg/day (2.5 mg for a 50 kg person).

Developmental toxicity (e.g., malformations of the vertebral bodies) was observed in the presence of maternal toxicity in rabbits with a no-effect level of 1 mg/kg/day. It is excreted in breast milk and has caused delayed development in nursing animals. It did not affect the reproductive system of male and female rats at very high doses.

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### Section 3: HAZARDS IDENTIFICATION (cont.)

In a 2-year oral toxicity study, urinary bladder papillomas in male rats at 20 mg/kg/day were observed. This is considered a drug class-effect in rats. Papillomas were not observed in female rats or in mice (both sexes). No bladder changes were observed in dogs or monkeys treated up to one year.

There was no evidence of mutagenic or genotoxic potential in a battery of *in vitro* and *in vivo* assays.

#### CARCINOGENICITY:

**NTP:** No ingredients listed.

**IARC:** No ingredients listed.

**OSHA:** No ingredients listed.

#### MEDICAL CONDITIONS AGGRAVATED BY OVEREXPOURE:

**Dorzolamide Hydrochloride:** Severe renal impairment

### Section 4: FIRST AID MEASURES

#### EYES:

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention if irritation occurs.

#### SKIN:

Wash contaminated area with soap and water. Get medical attention if irritation develops.

#### INGESTION:

Do NOT Induce Vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this product are swallowed, call a physician immediately. Provide product-prescribing information.

#### INHALATION:

No inhalation exposure expected with this formulation under normal conditions. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

#### ADDITIONAL NOTES TO PHYSICIAN:

For additional guidance, refer to the product-prescribing information. Contact the local Poison Control Center.

**Dorzolamide Hydrochloride:** Dorzolamide hydrochloride is a carbonic anhydrase inhibitor (decreases intraocular pressure). It is metabolized and excreted predominantly via the kidney. This material is a sulfonamide.

**Section 5: FIRE FIGHTING MEASURES**

**FLAMMABLE PROPERTIES:**

**Flash Point:** Not Applicable

**Method:** NA

**EXTINGUISHING MEDIA:**

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**HAZARDOUS COMBUSTION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride.

**SPECIAL FIRE FIGHTING INSTRUCTIONS:**

As in any fire, wear self-contained breathing apparatus and full protective gear.

**Section 6: ACCIDENTAL RELEASE MEASURES**

**General Information:**

Use appropriate protective equipment and engineering controls (refer to Section 8).

**Specific Information:**

Ventilate area. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Dispose of in accordance with Section 13.

**Section 7: HANDLING AND STORAGE**

**HANDLING:**

Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

**STORAGE:**

Store product at 15-30° (59-86°F). Protect from light.  
Shelf Life: Expiration date is listed on each package.

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### Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

#### ENGINEERING CONTROLS:

No special containment is required. Local exhaust ventilation should be provided when handling bulk liquids.

#### RESPIRATORY PROTECTION:

Not required during normal clinical use.

#### SKIN PROTECTION:

Not required during normal clinical use. Wash thoroughly with warm water and soap after handling. Impervious gloves are recommended when directly handling bulk liquids.

#### EYE PROTECTION:

Not required during normal clinical use. Appropriate eye protection is required when handling bulk liquids.

#### ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

No special recommendations during normal clinical use.

### Section 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL PROPERTIES:

**Appearance / Physical State:** Clear, colorless to nearly colorless. Sterile, isotonic buffered, slightly viscous, aqueous solution  
**Odor/Threshold Limit:** Not Available

#### CHEMICAL PROPERTIES:

<b>Boiling Point:</b>	Not Available	<b>Melting Point:</b>	Not Applicable
<b>Vapor Pressure:</b>	Not Available	<b>Vapor Density:</b>	Not Available
<b>Solubility In Water:</b>	<b>Dorzolamide Hydrochloride:</b> Soluble in water (41.1 g/L at 20°C) Slightly soluble in methanol and ethanol	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	1.0164 (Water = 1)
<b>pH:</b>	5.65	<b>Evaporation Rate:</b>	Not Available
<b>Freezing Point:</b>	Not Available	<b>Partition Coefficient:</b>	<b>Dorzolamide Hydrochloride:</b> Log Kow: 0.292
		<b>Molecular Weight:</b>	Not Available

### Section 10: STABILITY AND REACTIVITY

#### GENERAL:

Stable

#### CONDITIONS TO AVOID:

Not available

#### INCOMPATIBLE MATERIALS:

**Dorzolamide Hydrochloride:** Strong bases and oxidizing agents. Stainless steel.

**Section 10: STABILITY AND REACTIVITY (cont.)**

**HAZARDOUS POLYMERIZATION:**

Will not occur.

**HAZARDOUS DECOMPOSITION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride.

**Section 11: TOXICOLOGICAL INFORMATION**

**RTECS No.:** XJ9095163

**Dorzolamide Hydrochloride**

<b>Toxicity Data:</b>	ORL-RAT	LD50: 1927 MG/KG
<b>Toxicity Data:</b>	ORL-MOUSE	LD50: 1320 MG/KG

**RTECS No.:** FJ5958000

**Hydroxyethyl Cellulose**

**Toxicity Data:** INTRAPERITONEAL-MOUSE TDL<sub>0</sub>: 500 MG/KG

**RTECS No.:** OP2060000

**Mannitol**

**Toxicity Data:** ORL-RAT LD50: 13500 MG/KG

**RTECS No.:** BO3150000

**Benzalkonium Chloride**

**Toxicity Data:** ORL-RAT LD50: 50-500 MG/KG

**NOTE:** Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Refer to Section 3 for additional acute / chronic hazard information.

**Section 12: ECOLOGICAL INFORMATION**

**ENVIRONMENTAL EFFECTS:**

Practically non-toxic to aquatic organisms.

**Dorzolamide Hydrochloride:** Based upon the Activated Sludge Respiration Inhibition Test (ASRIT) EC50 results, concentrations less than 800 mg/L are not expected to upset an un-acclimated activated sludge system in a wastewater treatment plant.

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### Section 12: ECOLOGICAL INFORMATION (cont.)

#### ECOTOXICITY DATA:

<u>Component</u>	<u>Species</u>	<u>Period</u>	<u>Result</u>
Dorzolamide	<i>Daphnia magna</i> (LC50)	48 Hours	699 mg/L
Hydrochloride	Fathead minnow (LC50)	96 Hours	> 1000 mg/L

#### ENVIRONMENTAL FATE:

**Dorzolamide Hydrochloride:** Dorzolamide hydrochloride is not readily biodegradable. However, it is not likely to bioaccumulate or persist since the log Kow = 0.292 and the compound is soluble in water.

### Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

### Section 14: TRANSPORT INFORMATION

	<b>US DOT</b>	<b>IATA</b>	<b>IMO</b>	<b>RID/ADR</b>	<b>Canadian DG</b>
<b>Shipping Name:</b>	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
<b>Hazard Class:</b>	NA	NA			
<b>UN Number:</b>	NA	NA			
<b>Package Group:</b>	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

### Section 15: REGULATORY INFORMATION

#### OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Although technically exempt from the Occupational Safety & Health Administration (OSHA) Hazard Communication Standard, this product would be considered hazardous.

#### TOXIC SUBSTANCE CONTROL ACT (TSCA):

CAS# 9004-62-0 is listed on the TSCA inventory.

CAS# 69-65-8 is listed on the TSCA inventory.

CAS# 7732-18-5 is listed on the TSCA inventory.

#### SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed

SECTION 311, 312 (Hazard Categories): NA

SECTION 313 (Toxic Chemicals): No Components Listed

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### Section 15: REGULATORY INFORMATION (cont.)

#### **CALIFORNIA PROPOSITION 65:**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

### Section 16: OTHER INFORMATION

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