

SAFETY DATA SHEET

Dorzolamide HCL and Timolol Maleate Ophthalmic Solution, USP

1. Product and Company Information

Product Identifier: Dorzolamide HCL and Timolol Maleate Ophthalmic Solution, USP
 Synonyms: None
 National Drug Code: 70069- 051-01 (10 mL),
 Recommended Use: Ophthalmic solution
 Company: Somerset Therapeutics LLC
 Hollywood, FL 33024
 Contact Telephone: 1800-417-9175
 E-Mail:
 Emergency Phone Number: 1800-417-9175

2. Hazardous(s) Identification

Physical Hazards: None
 Health Hazards: None
 Symbol(s): None.
 Signal Word: None.
 Hazard Statement(s): None.
 Precautionary Statement(s): None.
 Hazards Not Otherwise Classified: None
 Supplementary Information: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

3. Composition and Information on Ingredients

Chemical Name	CAS Number
Dorzolamide Hydrochloride	130693-82-2
Timolol Maleate	26921-17-5
Benzalkonium chloride	8001-54-5
Sodium citrate di hydrate	6132-04-3
Mannitol USP	69-65-8
Sodium hydroxide NF	1310-73-2
Hydroxyethyl cellulose NF	9004-062-0
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret is required.

4. First Aid Measures

- Eye Contact** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
- Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
- Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
- Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves

5. Fire-Fighting Measures

- Extinguishing Media:** Water spray, carbon dioxide, dry chemical powder or ABC type.
- Hazardous Combustion Products:** Not determined.
- Fire Fighting Procedures:** Firefighters are recommended to wear self-contained breathing apparatus and full protective equipment. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.
- Fire / Explosion Hazards:** Not determined.

6. Accidental Release Measures

- Health and Safety Precautions:** Wear protective clothing, nitrile gloves and equipment consistent with the degree of hazard.
- Measures for Cleaning / Collecting:** Collect and place it in a suitable, properly labelled container for recovery or disposal.

Measures for Environmental Protections:

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and Storage:

- Handling:** Store container tightly closed in a cool, dry, well-ventilated location. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
- Storage:** Store the product 20 to 25°C (68 to 77°F).

8. Exposure Controls / Personal Protection

Exposure Limits	Common or Chemical Name	Employee Exposure Limits
	Dorzolamide Hydrochloride	0.04 mg/m ³ TWA
	Timolol Maleate	0.015 mg/m ³ TWA

Hands: Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy

Eyes: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Respiratory protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Skin protection Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

- Appearance:** Clear, colourless to nearly colourless.
- pH:** 5.4-5.9
- Decomposition Temperature (°C):** No data available.
- Evaporation Rate (Gram/s):** No data available
- Vapour Pressure (kPa):** No data available
- Vapour Density (g/ml):** >1
- Specific Gravity:** 1.02220 g/Cm³

Viscosity:	No data available
Flammability:	Not flammable
Flash Point (Liquid) (°C):	Not flammable
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under recommended storage conditions
Incompatible Materials:	Strong oxidizer
Hazardous Decomposition Products	Does not undergo explosive decomposition.
Hazardous Polymerization	Will not occur

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	Slightly toxic by ingestion. Harmful if swallowed.
Skin Contact:	No data available.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological

Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available
Acute Toxicity – Oral:	No data available
Acute Toxicity – Inhalation:	No data available
Corrosivity:	No data available
Dermal Irritation:	No data available
Eye Irritation:	No data available
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.

Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available

12. Ecological Information

Eco toxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bio accumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Conditions

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transportation Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name: N/A
IATA UN/ID No: N/A
IATA Hazard Class: N/A
IATA Packaging Group: N/A
IATA Label: N/A
IMDG - Not Regulated
IMDG Proper shipping Name: N/A
IMDG UN/ID No: N/A
IMDG Hazard Class: N/A
IMDG Flash Point: N/A
IMDG Label: N/A
DOT - Not Regulated
DOT Proper shipping Name: N/A
DOT UN/ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point: N/A
DOT Packing Group: N/A
DOT Label: N/A

15. Regulatory Information

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):**

Not listed.

**CERCLA Hazardous Substance
and Reportable Quantity:**

Not listed.

SARA 313:

Not listed.

SARA 302:

Not listed.

State Regulations

California Proposition 65:

Not listed.

FDA Designations:

Prescription only medication.

NDC No. 70069-051-01 (10 mL)

Other Information

NFPA Rating:

Health: 1

Flammability: 1

Reactivity: 0

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Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.