

SAFETY DATA SHEET
Timolol Maleate Ophthalmic Solution, USP



1. Identification

Product Identifier: Timolol Maleate Ophthalmic Solution, USP
Synonyms: Timolol hydrogen maleate
Recommended Use: Pharmaceutical.
Company: Somerset Therapeutics LLC
Somerset, NJ 08873
Customer Care: 1-800-417-9175

2. Hazard(s) Identification

Physical Hazards: Combustible liquid Category 4
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: Warning.
Hazard Statement(s): H227 Combustible liquid.
Precautionary Statement(s): P210 Keep away from flames and hot surfaces. No smoking.
P280 Wear protective gloves/eye protection/face protection.
P370 In case of fire: Use dry chemical, carbon dioxide + water spray or fog, and foam.
P378
P403 Store in a well-ventilated place. Keep cool.
+
P235
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

SAFETY DATA SHEET
Timolol Maleate Ophthalmic Solution, USP



3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Timolol Maleate USP	26921-17-5	Timolol hydrogen maleate	C ₁₃ H ₂₄ N ₄ O ₃ S•C ₄ H ₄ O ₄	432.50	0.25% and 0.5%

*The formula also contains Benzalkonium Chloride, NF 0.01% as a preservative. Dibasic Sodium Phosphate USP, Monobasic sodium phosphate USP, Sodium Hydroxide, NF to adjust pH and Water for Injection, USP.

4. First Aid Measures

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.

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.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Not determined.

Medical Conditions Aggravated by Exposure: Anaphylactic cross-reactions may occur. Appropriate measures should be taken if this occurs. Hypersensitivity to any of the ingredients of the medication.

SAFETY DATA SHEET



Timolol Maleate Ophthalmic Solution, USP

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

5. Firefighting Measures

Suitable Extinguishing Media: Dry chemical, carbon dioxide, water spray or fog, and foam on surrounding materials.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: When heated to decomposition, material emits toxic fumes.

Other Specific Hazards: Not determined.

**Special Protective Equipment/
Precautions for Firefighters:** As with all fires, evacuate personnel to safe area. Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: 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.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store at 15°C to 25°C (59°F to 77°F). Protect from freezing. Protect from light. After opening, timolol maleate ophthalmic solution can be used until the expiration date on the bottle..

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

SAFETY DATA SHEET
Timolol Maleate Ophthalmic Solution, USP



Occupational Exposure Guidelines:

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

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 Safety Data Sheets.

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 29CFR 1910.134). **WARNING:** Do not use air purifying respirators in oxygen depleted environments.

Eyes Protection:

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.

Hand Protection:

Not required for the normal use of this product. Chemically compatible gloves. 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.

Skin Protection:

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

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.

SAFETY DATA SHEET

Timolol Maleate Ophthalmic Solution, USP



9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless to slightly yellow solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	Approximately 7.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	>212°F.
Flash Point:	>200°F.
Evaporation Rate:	Same as water.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	As water.
Vapor Density:	>1.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Product has shelf life that is temperature dependent.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold. Avoid freezing.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	Toxic fumes when heated to decomposition.
Hazardous Polymerization:	Should not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May cause irritation to the respiratory tract. Avoid inhalation.
Ingestion:	No data available.
Skin Contact:	May cause skin irritation.

SAFETY DATA SHEET
Timolol Maleate Ophthalmic Solution, USP



Eye Contact:	May cause eye irritation.
Timolol Maleate:	It can cause hypersensitivity (anaphylactic) in some individuals. It also can cause skin and/or respiratory tract irritation. It is contraindicated in patients with bronchial asthma or severe chronic obstructive pulmonary disease, overt cardiac failure, cardiogenic shock, second or third degree atrioventricular shock, or sinus bradycardia. Adverse reactions include fatigue/tiredness, transient headache, chest pain, nausea, vomiting, dizziness, dyspnea, bronchial spasm, vertigo, palpitations, and eye irritation.
Sodium Phosphate Dibasic:	Dibasic sodium phosphate is widely used as an excipient in parenteral, oral, and topical pharmaceutical formulations. Oral consumption can cause gastrointestinal disturbances including diarrhea, nausea, and vomiting. These effects usually occur at doses that exceed the amount in pharmaceutical formulations. Dibasic sodium phosphate may be an irritant to the skin, eyes, and mucous membranes. Eye protection and gloves are recommended.
Sodium Phosphate Monobasic, Monohydrate:	Sodium phosphate Monobasic, Monohydrate is widely used as an excipient in parenteral, oral, and topical pharmaceutical formulations. Oral consumption can cause gastrointestinal disturbances including diarrhea, nausea, and vomiting. These effects usually occur at doses that exceed the amount in pharmaceutical formulations. Monobasic sodium phosphate, Monohydrate may be an irritant to the skin, eyes, and mucous membranes. Eye protection and gloves are recommended.
Benzalkonium Chloride:	It may cause eye and skin irritation. Harmful if swallowed. It causes gastrointestinal/digestive tract irritation and burn. It may affect behavior (central nervous system depression, depression) and metabolism. May produce burning pains in the mouth, throat, and abdomen, profuse salivation, and muscle weakness. May also affect the respiratory system and cardiovascular system, liver and kidneys. Inhalation may cause respiratory tract and mucous membrane irritation with sore throat, coughing, shortness of breath, and delayed lung edema. May affect material (mutagenic) and may cause adverse reproductive effects. Prolonged or repeated skin contact may cause dermatitis.
Sodium Hydroxide:	Sodium hydroxide solution is used for pH adjustment. It can cause severe skin and eye burn. Oral consumption may produce burns to the lips, oral cavity, upper airway, esophagus and possibly the digestive tract. Prolonged contact causes serious tissue damage. Repeated inhalation exposure to high concentrations of sodium hydroxide may lead to ulceration of the nasal passages.

SAFETY DATA SHEET



Timolol Maleate Ophthalmic Solution, USP

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 – Dermal:

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.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

Mutagenicity:

No data available.

Aspiration Hazard:

No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

No data available.

Terrestrial:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Mobility in Environment:

No data available.

Other Adverse Effects:

No data available.

13. Disposal Considerations

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

14. Transport Information

UN Number:

Not applicable.

Somerset Therapeutics, LLC. Somerset, NJ 08873

SAFETY DATA SHEET



Timolol Maleate Ophthalmic Solution, USP

UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

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.

16. **Other Information**

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