

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	:	Timolol Maleate Ophthalmic Solution USP 0.5%.
Chemical Family	:	Beta-adrenoceptor antagonist; antiglaucoma agent.
Synonyms	:	2-propanol, 1-(tert-butylamino-3-((4-morpholino-1,2,5-thiadiazol-3-yl)oxy)-, (-)-maleate
Manufacturer or supplier's details		
Details of the Supplier of the Safety Data Sheet	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

Physical Hazards	:	Combustible liquid.
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 + P378 In case of fire: Use dry chemical, carbon dioxide water spray or fog, and foam. P403 + P235 Store in a well-ventilated place. Keep cool. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazards Not Otherwise Classified	:	Not classifiable.
Supplementary Information	:	None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS*

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

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

SECTION 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).

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

SECTION 5 :FIRE FIGHTING 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.

SECTION 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.

SECTION 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 product upright in original containers with the cap tightly closed at a controlled room temperature 20°C – 25°C (68°F – 77°F). Store according to label and/or product insert information.
- Specific End Use** : Pharmaceuticals.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

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 29 CFR 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 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.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color	:	Clear, colorless to light 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.

SECTION 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

SECTION 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.
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.
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Sodium Phosphate Dibasic	:	Dibasic sodium phosphate is widely used
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	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.

**Symptoms Related to the
Physical, Chemical and
Toxicological Characteristics** :
**Delayed and Immediate
Effects of Exposure** :

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated

No data available

SECTION 12 : ECOLOGICAL INFORMATION

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.

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

UN Number : Not applicable.
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.

SECTION 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.

SECTION 16 : OTHER INFORMATION

Not made with natural rubber latex.

SDS creation date : June 08, 2024

SDS Revision date : NA

Version # : 00

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