


SAFETY DATA SHEET
Timolol Maleate Ophthalmic Solution, USP 0.5%

SECTION 1. IDENTIFICATION

Product Identification	:	Timolol Maleate Ophthalmic Solution, USP 0.5%			
Active Ingredient	:	(-)-1-(tert-Butylamino)-3-[(4-morpholino-1,2,5-thiadiazol-3-yl)oxy]-2-propanol maleate (1:1) (salt)			
Molecular formula	:	C ₁₃ H ₂₄ N ₄ O ₃ S·C ₄ H ₄ O ₄	Molecular Weight	:	432.50
CAS Number	:	26921-17-5			
Product Use	:	Pharmaceutical, Non-selective beta-adrenergic blocker			
Manufactured by	:	Holopack Verpackungstechnik GmbH (Rommelag CMO) Bahnhofstr., Sulzbach- Laufen, Germany (DEU), 74429	Manufactured for	:	Sentiss Pharma Private Limited 212, Ashirwad Commercial Complex, D-1, Green Park, New Delhi, Delhi, India (IND), 110016
Emergency Contact	:	1-855-573-6847			

SECTION 2. HAZARDS 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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Chemical Formula	Molecular Weight
Timolol Maleate	26921-17-5	C ₁₃ H ₂₄ N ₄ O ₃ S•C ₄ H ₄ O ₄	432.50

*The formula also contains Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Sodium Hydroxide to adjust pH and Purified Water.

SECTION 4. FIRST AID MEASURES

Ingestion	:	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
Eye Contact	:	The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
Skin Contact	:	Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required). Get medical attention immediately.
Inhalation	:	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
General information	:	Remove from exposure. Remove contaminated clothing. For treatment advice, get the guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

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

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	In case of fire, use water, dry chemical spray, chemical foam, or alcohol- resistant foam.
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

Remove any ignition source. Wear protective clothing, gloves and goggles. Pick up without raising dust. Keep contaminated material tightly closed containers. Wash with water. Don't throw this substance in sewer or ground water.		
Personal precautions, protective equipment and emergency procedures	:	For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk-through spilled material. Put on appropriate personal protective equipment. For emergency responders If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up	:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g., sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.
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SECTION 7. HANDLING AND STORAGE

Precautions for safe handling	:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for safe storage, including any incompatibilities		
Storage Conditions	:	Store at room temperature, 15 to 30°C (59 to 86°F). Protect from freezing. Protect from light. Because evaporation can occur through the unprotected polyethylene unit dose container and prolonged exposure to direct light can modify the product, the unit dose container should be kept in the protective foil overwrap and used within one month after the foil package has been opened.
Specific end use(s)	:	Pharmaceutical drug product for patients.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Control	:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protective Equipment	:	Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Respiratory protection	:	When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.
Hands protection	:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Eye protection	:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side shields.
Skin and protection	:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	Clear, colorless to light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	Approximately 7
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit/lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	1.00 – 1.02 g/mL
Solubility(is) Water solubility	:	soluble
Partition coefficient: n- octanol/water	:	No data available

Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	1 – 5 cps
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Stable under recommended storage conditions.
Chemical stability	:	Product has shelf life that is temperature dependent.
Conditions to avoid	:	Direct sunlight. Protect from freezing.
Incompatible materials	:	Oxidizing agents. Heat sources, direct sunlight.

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.
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	:	Sodium phosphate Monobasic 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 may be an irritant to the skin,

		eyes, and mucous membranes. Eye protection and gloves are recommended.
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:	:	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: Acute Toxicity – Dermal: Acute Toxicity – Inhalation Corrosivity Dermal Irritation Eye Irritation Sensitization Toxicokinetic/Metabolism Target Organ Effects Reproductive Effects Carcinogenicity	:	No data available. No data available. No data available. No data available. No data available. No data available. No data available. No data available. No data available. No data available. 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: Aspiration Hazard	:	No data available. No data available.

SECTION 12. ECOLOGICAL INFORMATION

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

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	No data available
Environmental hazards	:	No data available
Special precautions for user	:	No data available

SECTION 15. REGULATORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59- REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical	:	Not Available

SECTION 16. OTHER INFORMATION

Date of preparation: 13 JAN 2023

The information Contained in this material safety data sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this material safety data sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this material safety data sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet