
1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: ISTALOL 0.5% (Timolol Maleate Ophthalmic Solution)

Legal Category: Prescription only medicine, filled in bottle with controlled tip and overpacked inside a cardboard carton.

Drug Composition: Non-selective beta-adrenergic receptor blocking agent.

Manufactured for: ISTA Pharmaceuticals, Inc.

Address: 15279 Alton Parkway, Suite 100
Irvine, CA 92618

Information: Phone Number (M-F) 8am-5pm PST: (949) 788-6000

Emergency: Phone Number 24 hrs Infotrak 1-800-535-5053

Preparation Date: August 14, 2003 (Version 8.14.03 – 01)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m ³)	PEL(mg/m ³)	% Content
Timolol Maleate	26291-17-5	NE	NE	0.68
Purified Water	7732-18-5	NE	NE	>1

Ingredients <1% - Potassium Sorbate, Sodium Chloride, Sodium Phosphate Monobasic, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Plastic bottle with dropper tip in cardboard box. Clear colorless solution. Toxic by ingestion. **Accidental overexposure to ISTALOL 0.5% (Timolol Maleate Ophthalmic Solution) could cause symptoms typical of beta-adrenergic blocking agents, including severe respiratory reactions, severe cardiac reactions, headache, or dizziness.** Presents little or no hazard if spilled and no unusual hazard if involved in fire.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: Avoid contact with the eyes, unless prescribed by a physician. Eye contact will result in systemic absorption of the drug. Overexposure could result in adverse reactions associated with beta-adrenergic blocking agents, including severe cardiac reactions, severe respiratory reactions, headache, or dizziness.

Systemic: This drug is absorbed systemically. Excessive exposure could result in the adverse reactions described above in the Emergency Overview section.

Skin: Excessive exposure could result in the adverse reactions described above in the Emergency Overview section.

Ingestion: May cause nausea if ingested. Ingestion may result in systemic absorption of the drug, which could result in the adverse reactions described above in the Emergency Overview section.

Inhalation: There is low risk of inhalation, as this product is water-based and is not volatile.

Chronic Effects: Chronic exposure that results in topical or oral exposure could result in adverse reactions similar to those described in the Emergency Overview section, above. Chronic exposure should be avoided, unless prescribed by a physician.

Target Organs: NE.

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.
- Bronchial asthma
- Obstructive pulmonary disease
- Heart rhythm abnormalities
- Heart disease

4. FIRST AID MEASURES

Remove from exposure and in the event of any untoward events, obtain appropriate medical attention. Persons developing serious hypersensitivity reactions must receive immediate medical attention.

Eyes: May cause irritation. Flush immediately with copious amounts of water for at

least 20 minutes. Contact a physician if irritation persists or other symptoms develop.

Skin: May cause irritation. Remove all contaminated clothing and wash skin with soap and water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Flush out mouth with water. Contact physician immediately. Patients who have ingested the drug should be monitored for symptoms associated with exposure to beta-adrenergic blocking agents, as described in the Emergency Overview section, above, including respiratory, cardiac, or cardiopulmonary reactions.

Inhalation: There is low risk of inhalation, as this product is water-based and is not volatile. If inhalation of the liquid or aerosolized product does occur, it may cause irritation of respiratory tract. Avoid inhalation. Remove person to fresh air, and if breathing stops, use artificial respiration. Contact a physician.

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

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Flammable Limits: Lower flammable limit: N/A Upper flammable limit: N/A

Autoignition Temperature: None

Unusual Fire and Explosion Hazards: None.

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

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

Fire fighting Instructions: As with all fires, evacuate personnel to safe area. Firefighters should wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: 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.

7. HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

Handling: Avoid skin contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15⁰-30⁰ C (59⁰- 86⁰ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: None necessary in the home or clinical environment. 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 Material Safety Data Sheets.

Eye Protection: In the manufacturing plant, (29 CFR 1910.133) recommend goggles or chemical safety glasses.

Skin Protection: In the manufacturing plant, wear thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: Do not use air purifying respirators in oxygen depleted environments. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

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.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Clear, colorless to pale yellow solution, odorless.		
Boiling Point:	NA	Evaporation Rate:	NE
Specific Gravity:	As Water	Vapor Density:	As Water
Vapor Pressure:	As Water	Viscosity:	NE
Water Solubility:	Soluble	pH:	Approx. 7

10. STABILITY AND REACTIVITY

Chemical Stability: Product has shelf life that is temperature dependent.

Conditions to avoid: Extreme heat or cold. Avoid freezing.

Incompatibility: No data.

Hazardous Decomposition Products: Toxic fumes when heated to decomposition.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to raw materials used to manufacture the product. Concentrations and toxicological effects are substantially reduced in the ophthalmic solution product. For more detailed information see MSDS on the specific chemical raw material.

CAS #

26291-17-5 **Timolol Maleate**

Can cause hypersensitivity (anaphylactic) in some individuals. Can cause skin and/or respiratory tract irritation. 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, eye irritation.

7558-79-4 **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.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. (not yet issued)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

NA – Not Applicable

< - Less Than

> - Greater Than