Safety Data Sheet (SDS)
3 Pearl Court
Allendale, NJ 07401
(800) 521-5340

Timolol Maleate Sterile Ophthalmic Solution USP 0.25% & 0.50%

Section 1: Identification

Common Name: Timolol Maleate Sterile Ophthalmic Solution
Brand Name: Timoptic®
Formula: $C_{13}H_{24}N_4O_3S \cdot C_4H_4O_4$
CAS Number: 26921-17-15
Therapeutic Category: Beta-adrenoceptor antagonist; anti-glaucoma agent
Chemical Name: 2-propanol, 1-(tert-butylamino-3-((4-morpholino-1,2,5-thiadiazol-3-yl)oxy)-,(-)-maleate
Manufacturer Name & Address: FDC Limited 142-48 S. W. Road Jogeshwari (West) Mumbai – 400 102 Marharashtra, India
Distributor Name & Address: Rising Pharmaceuticals, Inc. 3 Pearl Court Allendale, NJ 07401
Emergency Phone Number/Adverse Reactions/Product Complaints/Product Inquiries: 1-866-562-4597
Recommended Use: For Ophthalmic Use Only
Restriction of Use: For Ophthalmic Use Only

Section 2: Hazard(s) Identification

Chemical Hazards: N/A
Required Label Elements: N/A

Section 3: Composition/Information on Ingredients

Chemical Ingredients: Timolol Maleate, Monobasic and Dibasic Sodium Phosphate, Sodium Chloride, Sodium Hydroxide (to adjust pH) and Water for Injection. Benzalkonium Chloride added as preservative.
Trade Secret Claim(s): N/A

Section 4: First-Aid Measures

Important Symptoms/effects, acute, delayed: N/A
Required Treatment: N/A
General First-Aid Measures: If swallowed, wash out mouth with water provided person is conscious. Call a physician.
Eye First-Aid Measures: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.
Skin First-Aid Measures: In case of contact, wash affected skin with soap and water. Contact a physician if skin irritation develops.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Techniques & Equipment: N/A
Chemical Hazards from Fire: N/A
Flash Point: N/A
Combustible Material: May combust at high temperatures
Explosive Material: N/A
Flammable Material: N/A

Section 6: Accidental Release Measures

Emergency Procedures: N/A
Protective Equipment: N/A
Proper Methods of Containment & Cleanup: Spills should be cleaned up by a proper tool and disposed into a waste container. After, pour some water at spill sight.

Section 7: Handling & Storage

Precautions for Safe Handling & Storage: Keep this and all drugs out of reach of children. Store in a cool, well ventilated area, away from excessive heat. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug.
Handling & Storage Incompatibilities: N/A
Storage Temperature Conditions: 20 – 25 °C (68 – 77 °F) See USP Controlled Room Temperature
Engineering Control: N/A
Respiratory Protection: N/A
Skin Protection: N/A
Eye Protection: N/A

Section 8: Exposure Controls/Personal Protection

OSHA's Permissible Exposure Limits (PELs): N/A
Threshold Limit Values (TLVs): N/A
Appropriate Engineering Controls: N/A
Personal Protection Equipment (PPE): N/A

Section 9: Physical & Chemical Properties

Chemical's Characteristics: N/A
Melting Point: N/A
Molecular Weight: 432.49
Appearance: Clear, colorless solution
Odor: Odorless
Solubility in Water: Insoluble

Section 10: Stability & Reactivity

Chemical Stability: Stable
Possibility of Hazardous Reactions: When heated to decomposition, toxic fumes will emit.

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Section 11: Toxicological Information

Routes of Exposure: N/A
Related symptoms, acute & chronic effects: N/A
Numerical Measures of Toxicity: N/A

Section 12: Ecological Information

Exotoxicity: N/A
Mutagenicity: N/A
Environmental Fate: N/A
Degradability: N/A
LD_{50}/(Oral)*: 1028 mg/kg
Reproductive Effects: N/A
Carcinogenicity: N/A
Mutagenicity: N/A

Section 13: Disposal Considerations

Spills/Leaks: Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pick up is complete.
Waste Disposal Method: Incineration is recommended. Waste disposal should be in accordance with existing federal, state and local environment control laws.

Section 14: Transport Information

IATA/ICAO – Non Hazardous – Not Regulated
IATA Proper Shipping Name: N/A
IATA UN/ID No: N/A
IATA Hazard Class: N/A
IATA Packing Group: N/A
IATA Label: N/A

IMDG – Non Hazardous – Not Regulated
IMDG Proper Shipping Name: N/A
IMDG UN/ID No: N/A
IMDG Hazard Class: N/A
IMDG Packing Group: N/A
IMDG Label: N/A

DOT – Non Hazardous – Not Regulated
DOT Proper Shipping Name: N/A
DOT UN/ID No: N/A
DOT Hazard Class: N/A
DOT Packing Group: N/A
DOT Label: N/A

Section 15: Regulatory Information

NDC Number(s): 64980-513-05 (0.25% - 5mL)
64980-513-01 (0.25% - 10mL)
64980-513-15 (0.25% - 15mL)

64980-514-05 (0.5% - 5mL)
64980-514-01 (0.5% - 10mL)
64980-514-15 (0.5% - 15mL)

Section 16: Other Information

New: (04/20/2015)
Rev 1: (06/24/2015)

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*Data for Active Pharmaceutical Ingredient