


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	TIMOLOL MALEATE, USP
PRODUCT CODE	0366
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Eye Irritation (Category 2B) Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	Harmful if swallowed Causes eye irritation Suspected of causing cancer Toxic to aquatic life. Repeated exposure may cause skin dryness or cracking.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S)	Prevention Wash hands thoroughly after handling. Do not touch eyes. Do not eat, drink or smoke when using this product Avoid release to the environment. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection

HMIS CLASSIFICATION	Response	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help. IF EXPOSED OR CONCERNED: Get medical advice.		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	Health Hazard	1	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2-Propanol, 1-(1,1-dimethylethyl)amino-3-[[4-(4-morpholinyl)-1,2,5-thiadiazol-3-yl]oxy]-, (S)-, (Z)-2-butenedioate(1:1)(Salt)
BOTANICAL NAME	Not applicable
SYNONYM	Timolol hydrogen maleate
CHEMICAL FORMULA	C ₁₃ H ₂₄ N ₄ O ₃ S · C ₄ H ₄ O ₄
CHEMICAL FAMILY	Morpholine derivative
CAS NUMBER	26921-17-5
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	432.4952

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
TIMOLOL MALEATE	26921-17-5	248-111-5	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
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FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: TIMOLOL MALEATE CAS #: 26921-17-5

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial: TWA: 10 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White to practically white, odorless or practically odorless powder.

SOLUBILITY

Soluble in water, in alcohol, and in methanol; sparingly soluble in chloroform and in propylene glycol; insoluble in ether and in cyclohexane.

ODOR

Odorless or practically odorless.

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

(199-203)°C,
(390.2-397.4)°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

(199-203)°C,
(390.2-397.4)°F
(decomposes)

PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	3.8 - 4.3 (2%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 900 - 1800 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available								
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Local Effects: Rabbit: Skin irritation; Result: Negative.								
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation Local Effects: Rabbit: Eye irritation; Result: Negative; Severity: Slight.								
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.								
SKIN SENSITIZATION	Due to lack of data the classification is not possible.								
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Suspected mutagen: The Toolbox profiler Proteinbinding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity								
CARCINOGENICITY	<table border="1"> <tr> <td>OSHA</td> <td>TIMOLOL MALEATE is not listed.</td> </tr> <tr> <td>NTP</td> <td>TIMOLOL MALEATE is not listed.</td> </tr> <tr> <td>IARC</td> <td>TIMOLOL MALEATE is not evaluated.</td> </tr> <tr> <td>California Proposition</td> <td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td> </tr> </table>	OSHA	TIMOLOL MALEATE is not listed.	NTP	TIMOLOL MALEATE is not listed.	IARC	TIMOLOL MALEATE is not evaluated.	California Proposition	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
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IARC	TIMOLOL MALEATE is not evaluated.								
California Proposition	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.								

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
 Rat: 300 mg/kg/day Carcinogenicity (2 years). Result: Increase in adrenal pheochromocytomas in males.
 Mouse: 500 mg/kg/day Carcinogenicity, Lifetime study. Result: Increase in malignant pulmonary tumors and mammary adenocarcinomas in females.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
 Some beta-adrenergic blocking agents have been reported to cause fetal and neonatal bradycardia, hypotension, and hypoglycemia when administered during pregnancy, and may also be associated with fetal growth retardation.
 Mouse: 1000 mg/kg/day Reproductivity / developmental. Result: Maternal toxicity and increased fetal resorptions.
 Rat: 50 mg/kg/day Reproductivity / developmental. Result: Not teratogenic; caused delayed ossification.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:
 Not available
DELAYED HEALTH EFFECT FROM EXPOSURE:
 Beta-adrenergic blockers: Cardiovascular effects. Hypotension. Respiratory depression or arrest. Coma.

 Symptoms related to the physical, chemical, and toxicological characteristics:
 Beta-adrenergic blockers: Nausea. Vomiting. Dizziness. Difficulty breathing. Headache. Mood or mental changes. Drowsiness. Weakness. Slow heartbeat. Insomnia. Cold hands and feet. Sexual dysfunction. Stomach upset. Nervousness. Vision disturbances. Swelling of feet or legs. Muscle, joint, or chest pain. Seizures.

 Cross sensitivity: Persons sensitive to other beta-adrenergic blocking agents may be sensitive to this material also.

POTENTIAL HEALTH EFFECTS

Medical conditions aggravated by exposure:
 Beta-adrenergic blockers: Heart disorders. Hypotension. Peripheral vascular disease. Respiratory disorders. Psoriasis. History of allergies. Type 1 diabetes. Hyperthyroidism. Depression.
 Pheochromocytoma. Impaired liver or kidney function.

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	Causes eye irritation.

NOTES

Pharmacologically active material. Occupational exposure may cause physiological effects.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea:Daphnia (mg/L): 10.27*
 LC50: 96 Hr: Fish: Pimephales promelas (mg/L): 411
 EC50: 96 Hr: Green Algae: (mg/L): 8.97*

PERSISTENCE AND DEGRADABILITY

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as nonreadily biodegradable

BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Soluble in water: 33.3 - 100 g/L
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment
NOTES	*The Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

<u>AUSTRALIA</u> HAZCHEM	Not applicable
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<u>EU</u> TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
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ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A Appendix B		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
TIMOLOL MALEATE 26921-17-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.