according to the Globally Harmonized System



## **Timolol Formulation**

**Revision Date:** Date of last issue: 25.01.2024 Version SDS Number: 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name **Timolol Formulation** 

Manufacturer or supplier's details

Company : MSD

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical Restrictions on use Not applicable

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

repeated exposure

Specific target organ toxicity - : Category 1 (Cardio-vascular system, Lungs)

**GHS** label elements

Hazard pictograms

Signal word

Hazard statements H372 Causes damage to organs (Cardio-vascular system,

Lungs) through prolonged or repeated exposure.

Precautionary statements Prevention:

P260 Do not breathe mist or vapours.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

according to the Globally Harmonized System



## **Timolol Formulation**

**Revision Date:** Date of last issue: 25.01.2024 Version SDS Number: 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Response:

P319 Get medical help if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

### Components

Chemical name	CAS-No.	Concentration (%	
		w/w)	
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	>= 0.1 - < 1	

#### 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Causes damage to organs through prolonged or repeated

exposure.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

according to the Globally Harmonized System



## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Phosphorus compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

according to the Globally Harmonized System



## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
(S)-3-[3-(tert-butylamino)-2- hydroxypropoxy]-4- morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Eye, Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	

**Engineering measures** : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-less

quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

according to the Globally Harmonized System



## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : Colorless to pale yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

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

Vapour pressure : No data available

according to the Globally Harmonized System



## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Relative vapour density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle characteristics

Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of :

exposure

Inhalation Skin contact Ingestion

Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Acute oral toxicity : LD50 (Rat): 1,000 mg/kg

LD50 (Mouse): 1,140 mg/kg

according to the Globally Harmonized System



## **Timolol Formulation**

Version **Revision Date:** Date of last issue: 25.01.2024 SDS Number: 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

Acute toxicity (other routes of : LD50 (Mouse): 300 mg/kg

administration)

Application Route: Intraperitoneal

LD50 (Mouse): 800 mg/kg

Application Route: Subcutaneous

### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species Rabbit Method **Draize Test** Result No skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species Rabbit

Result Mild eye irritation

**Species** Dog

Result No eye irritation

### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

# (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo Test Type: In vivo micronucleus test

Species: Mouse

Method: OECD Test Guideline 474

Result: negative

according to the Globally Harmonized System



## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

### Carcinogenicity

Not classified based on available information.

#### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

LOAEL : 300 mg/kg body weight

Result : negative Target Organs : Adrenal gland

Remarks : The significance of these findings for humans is not certain.

Species : Mouse, female

Application Route : Oral Exposure time : 18 Months

LOAEL : 500 mg/kg body weight

Result : negative

Target Organs : Lungs, Mammary gland, Uterus (including cervix)

Remarks : The significance of these findings for humans is not certain.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

## Reproductive toxicity

Not classified based on available information.

#### Components:

## (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Oral

Fertility: NOAEL Mating/Fertility: 150 mg/kg body weight Early Embryonic Development: NOAEL F1: 150 mg/kg body

weight

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Developmental Toxicity: LOAEL F1: 50 mg/kg body weight Result: Some evidence of adverse effects on development,

based on animal experiments.

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

### STOT - single exposure

Not classified based on available information.

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## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

### STOT - repeated exposure

Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

#### **Product:**

Target Organs : Cardio-vascular system, Lungs

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Components:

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Target Organs : Lungs, Cardio-vascular system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species : Rat

NOAEL : 25 mg/kg

Application Route : Oral

Exposure time : 67 Weeks

Species : Dog

NOAEL : 10 mg/kg

Application Route : Oral

Exposure time : 54 Weeks

Target Organs : Kidney

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

### **Product:**

General Information : May cause

Stomach/intestinal disorders

Respiratory disorders

Symptoms: Irregular cardiac activity, central nervous system

effects

Eye contact : Symptoms: burning or stinging of the eye

#### Components:

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Eye contact : Symptoms: burning or stinging of the eye, dryness of the

eyes, Headache, Nausea, Dizziness, dry mouth, changes in

libido, hair loss, Allergic reactions

Ingestion : Symptoms: Headache, Fatigue, Respiratory disorders, Gas-

trointestinal discomfort, Allergic reactions, Rash, hair loss,

altered mental status, Dizziness, changes in libido

according to the Globally Harmonized System



## **Timolol Formulation**

**Revision Date:** Date of last issue: 25.01.2024 Version SDS Number: 28.09.2024 1609213-00016 Date of first issue: 01.05.2017 3.0

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

#### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 411 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 161 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

EC50 (Photobacterium phosphoreum): > 1,800 mg/l

### Persistence and degradability

#### **Components:**

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 0 % Exposure time: 30 d

Stability in water : Hydrolysis: 0 %(61 d)

Method: FDA 3.09

### **Bioaccumulative potential**

### Components:

## (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Partition coefficient: n-

octanol/water

: log Pow: 1.48

#### Mobility in soil

No data available

### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

## **Disposal methods**

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

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## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

#### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

### **16. OTHER INFORMATION**

Revision Date : 28.09.2024

**Further information** 

Sources of key data used to compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

## Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with

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## **Timolol Formulation**

Version Revision Date: SDS Number: Date of last issue: 25.01.2024 3.0 28.09.2024 1609213-00016 Date of first issue: 01.05.2017

x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan): ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals: SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN