

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Timolol Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
20 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification


#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - repeated exposure, Category 1, Cardio-vascular system, Lungs	H372: Causes damage to organs through prolonged or repeated exposure.
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#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Danger

Hazard statements : H372 Causes damage to organs (Cardio-vascular system, Lungs) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version 2.9      Revision Date: 09.04.2021      SDS Number: 1609215-00011      Date of last issue: 10.10.2020  
Date of first issue: 01.05.2017

P314 Get medical advice/ attention if you feel unwell.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5 248-111-5	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Lungs, Cardio-vascular system)	>= 0.1 - < 1

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- 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).
- 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

---

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes damage to organs through prolonged or repeated exposure.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides  
Phosphorus compounds

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

---

barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for 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 absorbent.  
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 determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
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 assessment  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.  
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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.  
Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version 2.9      Revision Date: 09.04.2021      SDS Number: 1609215-00011      Date of last issue: 10.10.2020  
Date of first issue: 01.05.2017

Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

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

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Disodium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	4.07 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	3.04 mg/m <sup>3</sup>

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Disodium hydrogenorthophosphate	Fresh water	0.05 mg/l
	Marine water	0.005 mg/l
	Intermittent use/release	0.5 mg/l
	Sewage treatment plant	50 mg/l

### 8.2 Exposure controls

#### Engineering measures

Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

#### Personal protective equipment

Eye protection : Wear the following personal protective equipment:  
Safety glasses  
Equipment should conform to BS EN 166

Hand protection

Material : Chemical-resistant gloves

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

---

Remarks	: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic 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
Relative vapour density	: No data available
Density	: No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

---

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.

### 9.2 Other information

Molecular weight : Not applicable  
Particle size : Not applicable

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version 2.9      Revision Date: 09.04.2021      SDS Number: 1609215-00011      Date of last issue: 10.10.2020  
Date of first issue: 01.05.2017

---

### 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

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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version 2.9      Revision Date: 09.04.2021      SDS Number: 1609215-00011      Date of last issue: 10.10.2020  
Date of first issue: 01.05.2017

---

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Method: OECD Test Guideline 474  
Result: negative

### **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 - Assessment : Weight of evidence does not support classification as a carcinogen

### **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 development : 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 - Assessment : Some evidence of adverse effects on development, based on animal experiments.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version 2.9      Revision Date: 09.04.2021      SDS Number: 1609215-00011      Date of last issue: 10.10.2020  
Date of first issue: 01.05.2017

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### STOT - single exposure

Not classified based on available information.

### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

Ingestion : eyes, Headache, Nausea, Dizziness, dry mouth, changes in libido, hair loss, Allergic reactions  
: Symptoms: Headache, Fatigue, Respiratory disorders, Gastrointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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

Toxicity to daphnia and other aquatic invertebrates : 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

### 12.2 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

### 12.3 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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, : Conditions of restriction for the following entries should be considered:

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

preparations and articles (Annex XVII)	Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	: Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	: Not applicable

### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information	: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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### Full text of H-Statements

H302	: Harmful if swallowed.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.

### Full text of other abbreviations

Acute Tox.	: Acute toxicity
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada);

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.9	09.04.2021	1609215-00011	Date of first issue: 01.05.2017

ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

STOT RE 1                      H372

### Classification procedure:

Based on product data or assessment

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.

GB / EN