

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Timolol Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

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

GHS label elements

Hazard pictograms :



Signal word : Danger

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 skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P314 Get medical advice/ attention if you feel unwell.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
 Date of first issue: 2017/05/01

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)	ENCS No.
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	$\geq 0.1 - < 1$	
Benzo decinium bromide	7281-04-1	$\geq 0.0025 - < 0.025$	1-105 / 3-2694, 3-326 / 1-105
Benzo dodecinium chloride	139-07-1	$\geq 0.0025 - < 0.025$	1-215 / 3-2694, 3-326 / 1-215
Miristalkonium chloride	139-08-2	$\geq 0.0002 - < 0.0025$	3-2694 / 1-215, 1-215 / 3-326

4. 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.
- 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).
- Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

		Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Phosphorus compounds
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.
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 emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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 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.

7. HANDLING AND STORAGE

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.

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
 Date of first issue: 2017/05/01

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.

Avoidance of contact : Oxidizing agents
 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.

Storage

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
 Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

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

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
 Filter type : Particulates type
 Hand protection
 Material : Chemical-resistant gloves
 Remarks : Choose gloves to protect hands against chemicals depending

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

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.

Eye protection : Wear the following personal protective equipment:
Safety glasses

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).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: Aqueous solution
Colour	: Colorless to pale yellow
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: No data available
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: No data available
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle characteristics	:	Not applicable
Particle size	:	Not applicable

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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

Acute toxicity (other routes of administration)	:	LD50 (Mouse): 300 mg/kg
		Application Route: Intraperitoneal
		LD50 (Mouse): 800 mg/kg

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

Application Route: Subcutaneous

Benzodocinium bromide:

Acute oral toxicity : LD50 (Rat): 230 mg/kg
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.
Acute dermal toxicity : LD50 (Rabbit): > 2,000 - 5,000 mg/kg
Remarks: Based on data from similar materials

Benzododecinium chloride:

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg
Remarks: Based on data from similar materials
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Miristalkonium chloride:

Acute oral toxicity : LD50 (Rat): 397.5 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): 3,412 mg/kg
Remarks: Based on data from similar materials

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

Benzodocinium bromide:

Species : Rabbit
Result : Corrosive after 4 hours or less of exposure
Remarks : Based on data from similar materials

Benzododecinium chloride:

Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure
Remarks : Based on data from similar materials

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

Miristalkonium chloride:

Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure
Remarks : Based on data from similar materials

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

Benzodocinium bromide:

Species : Rabbit
Result : Irreversible effects on the eye
Remarks : Based on data from similar materials

Benzododecinium chloride:

Species : Rabbit
Result : Irreversible effects on the eye
Remarks : Based on data from similar materials

Miristalkonium chloride:

Species : Rabbit
Result : Irreversible effects on the eye
Remarks : Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Benzodocinium bromide:**

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Benzododecinium chloride:

Test Type : Buehler Test

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Exposure routes : Skin contact
 Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : negative
 Remarks : Based on data from similar materials

Miristalkonium chloride:

Test Type : Buehler Test
 Exposure routes : Skin contact
 Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : negative
 Remarks : Based on data from similar materials

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

Benzodecinium bromide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Method: OECD Test Guideline 471
 Result: negative
 Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
 Method: OECD Test Guideline 476
 Result: negative
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
 Method: OECD Test Guideline 473
 Result: negative
 Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
 Species: Mouse
 Application Route: Ingestion
 Method: OECD Test Guideline 474
 Result: negative
 Remarks: Based on data from similar materials

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

Benzododecinium chloride:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Miristalkonium chloride:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
 Date of first issue: 2017/05/01

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

Benzodecinium bromide:

Species : Rat
 Application Route : Ingestion
 Exposure time : 2 Years
 Method : OECD Test Guideline 453
 Result : negative
 Remarks : Based on data from similar materials

Benzododecinium chloride:

Species : Rat
 Application Route : Ingestion
 Exposure time : 104 weeks
 Method : OECD Test Guideline 453
 Result : negative
 Remarks : Based on data from similar materials

Miristalkonium chloride:

Species : Rat
 Application Route : Ingestion
 Exposure time : 2 Years
 Method : OECD Test Guideline 453
 Result : negative
 Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

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

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

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.

Benzodecinium bromide:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: negative
 Remarks: Based on data from similar materials

Benzododecinium chloride:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: negative
 Remarks: Based on data from similar materials

Miristalkonium chloride:

Effects on fertility : Test Type: Two-generation study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative
 Remarks: Based on data from similar materials

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: negative
 Remarks: Based on data from similar materials

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

Benzododecinium chloride:

Species : Rat
 NOAEL : > 25 mg/kg
 Application Route : Ingestion
 Exposure time : 52 Weeks
 Method : OECD Test Guideline 453
 Remarks : Based on data from similar materials

Miristalkonium chloride:

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Species	:	Rat
NOAEL	:	56 - 65 mg/kg
LOAEL	:	109 - 133 mg/kg
Application Route	:	Ingestion
Exposure time	:	52 Weeks
Remarks	:	Based on data from similar materials

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, Gastrointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido

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
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

Benzodecinium bromide:

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 48 h
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 0.001 - 0.01 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 10

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 0.01 - 0.1 mg/l
Exposure time: 28 d
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 10 - 100 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Benzododecinium chloride:

Toxicity to fish : LC50 : > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50: > 0.01 - 0.1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

EC10: > 0.001 - 0.01 mg/l
 Exposure time: 72 h
 Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 10
 Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 0.01 - 0.1 mg/l
 Exposure time: 28 d
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 0.001 - 0.01 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
 Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1
 Toxicity to microorganisms : EC50: > 10 - 100 mg/l
 Exposure time: 30 min
 Method: OECD Test Guideline 209
 Remarks: Based on data from similar materials

Miristalkonium chloride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.85 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.016 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.049 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0012 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 10
 M-Factor (Chronic aquatic toxicity) : 1
 Toxicity to microorganisms : EC10: 4 mg/l
 Exposure time: 30 min
 Method: OECD Test Guideline 209
 Remarks: Based on data from similar materials

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

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

Benzodecinius bromide:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Benzododecinius chloride:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Miristalkonium chloride:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 95.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

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

Benzodecinius bromide:

Partition coefficient: n-octanol/water : log Pow: < 4
Remarks: Expert judgement

Benzododecinius chloride:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: < 4
Remarks: Expert judgement

Miristalkonium chloride:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 79

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

Remarks: Based on data from similar materials

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

- | | | |
|------------------------|---|---|
| Waste from residues | : | Dispose of in accordance with local regulations.
Do not dispose of waste into sewer. |
| 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. |
-

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

- | | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |

IATA-DGR

- | | | |
|--|---|----------------|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

IMDG-Code

- | | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |
| Marine pollutant | : | Not applicable |

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
 Date of first issue: 2017/05/01

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Salt of alkyl(C=12-16)(benzyl)(dimethyl)ammonium	184

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Timolol Formulation

Version 6.1 Revision Date: 2023/04/04 SDS Number: 1598367-00015 Date of last issue: 2022/10/01
Date of first issue: 2017/05/01

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**Until March 31st, 2023**

Not applicable

From April 1st, 2023

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**Further information**

Timolol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
6.1	2023/04/04	1598367-00015	Date of first issue: 2017/05/01

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIIC - 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 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; TECL - 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.

JP / EN