Timolol Formulation



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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

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 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:





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

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. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

In case of eye contact

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).





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Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Water spray Suitable extinguishing media

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

None known.

Specific hazards during fire-

fiahtina

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, protec- :

tive 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-

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.





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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.

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.

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/m3 (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.





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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 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.

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 / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available





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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)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density and / or relative density

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

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 : No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

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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 : LD50 (Mouse): 300 mg/kg

administration)

Application Route: Intraperitoneal

LD50 (Mouse): 800 mg/kg

Application Route: Subcutaneous

Benzodecinium bromide:

Acute oral toxicity : LD50 (Rat): 230 mg/kg

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

LD50 (Rabbit): > 2,000 - 5,000 mg/kgAcute dermal toxicity

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.





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Components:

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

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

Benzodecinium 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

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

Benzodecinium 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





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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:

Benzodecinium 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 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





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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

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





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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.

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

Benzodecinium bromide:

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

Method : OECD Test Guideline 453





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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:

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: Test Type: Embryo-foetal development

ment

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.

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 develop: Test Type: Embryo-foetal development





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ment 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 develop-

ment

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

Effects on foetal develop-

ment

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.



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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:

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





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Eve contact Symptoms: burning or stinging of the eve

Components:

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

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

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

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

Benzodecinium bromide:

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 ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials





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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 tox- :

city

10

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): > 0.01 - 0.1

mg/

Exposure time: 28 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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)

Toxicity to microorganisms : EC50: > 10 - 100 mg/l

: 1

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

EC10: > 0.001 - 0.01 mg/l Exposure time: 72 h

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox- :

city)

: 10

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

NOEC (Daphnia magna (Water flea)): > 0.001 - 0.01 mg/l

Exposure time: 21 d





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ic toxicity) Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

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 tox- : 10

icity)

M-Factor (Chronic aquatic : 1

toxicity)

Toxicity to microorganisms

: EC10: 4 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

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





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

Method: FDA 3.09

Benzodecinium bromide:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Benzododecinium 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

Benzodecinium bromide:

Partition coefficient: n-

octanol/water

log Pow: < 4

Remarks: Expert judgement

Benzododecinium 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

Remarks: Based on data from similar materials

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable





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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 han-

dling 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 : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

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

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.





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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

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

Not applicable





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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

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

Not classified as noxious liquid substance Bulk transportation

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

compile the Safety Data

Sheet

Sources of key data used to : 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.





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Date format : yyyy/mm/dd

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 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.

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