

Timolol / Dorzolamide Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 11.0 2024/09/28 28813-00025 Date of first issue: 2014/11/06

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Timolol / Dorzolamide 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, Central nervous system,

Gastrointestinal tract, Lungs)

GHS label elements

Hazard pictograms :

Signal word : Danger

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

tral nervous system, Gastrointestinal tract, Lungs) through pro-

longed 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.



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Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Dorzolamide	130693-82-2	>= 1 - < 10	-
(S)-3-[3-(tert-butylamino)-2- hydroxypropoxy]-4-morpholino- 1,2,5-thiadiazole monomaleate	26921-17-5	>= 0.1 - < 1	-
Benzododecinium chloride	139-07-1	>= 0.0025 - < 0.025	1-215 / 3-2694, 3-326 / 1-215
Miristalkonium chloride	139-08-2	>= 0.0025 - < 0.025	1-215 / 3-2694, 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.

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. Causes damage to organs through prolonged or repeated

Most important symptoms and effects, both acute and

delaved

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

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Sulphur oxides

Hydrogen chloride

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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

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

SO.

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

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

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

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

bent.

Local or national regulations may apply to releases and dis-



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posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

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. Oxidizing agents

Avoidance of contact

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

flushing systems and safety showers close to the working

place.

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

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

use of administrative controls.

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	Control parame-	Basis
		(Form of	ters / Concentra-	
		exposure)	tion standard /	



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			Permissible con- centration		
Dorzolamide	130693-82-2	TWA	10 μg/m3 (OEB 3)	Internal	
	Further information: Eye				
		Wipe limit	100 μg/100 cm ²	Internal	
(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 : Use appropriate engineering controls and manufacturing

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

less quick connections).

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

protect products, workers, and the environment.

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

tainment devices).

Minimize open handling.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : colourless



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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

Decomposition temperature No data available

pΗ 5.6

No data available Evaporation rate

No data available Auto-ignition temperature

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

Relative density 1.02

No data available Density

Relative vapour density No data available

Explosive properties Not explosive



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

Molecular weight No data available

Particle characteristics

Particle size No data available

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

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: Inhalation

exposure Skin contact

Ingestion Eve contact

Acute toxicity

Not classified based on available information.

Product:

Acute toxicity estimate: > 2,000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Dorzolamide:

Acute oral toxicity : LD50 (Rat): 1,927 mg/kg

LD50 (Mouse): 1,320 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

(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



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administration) Application Route: Intraperitoneal

LD50 (Mouse): 800 mg/kg

Application Route: Subcutaneous

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: RabbitMethod: Draize TestResult: No skin irritation

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.



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Components:

Dorzolamide:

Species : Monkey

Result : Mild eye irritation

(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

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:

Dorzolamide:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : Weak sensitizer

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



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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:

Dorzolamide:

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: negative

Test Type: Alkaline elution assay Test system: rat hepatocytes

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster fibroblasts

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay

Species: Mouse Result: negative

(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

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



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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.

Components:

Dorzolamide:

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

20 mg/kg body weight

Result : negative

Remarks : The mechanism or mode of action may not be relevant in

humans.



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Species : Mouse Application Route : Oral

Exposure time : 21 month(s)
Result : negative

(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- : Weight of evidence does not support classification as a car-

ment cinogen

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:

Dorzolamide:

Effects on fertility : Test Type: Fertility

Species: Rat, male and female

Application Route: Oral



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Fertility: NOAEL: 7.5 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 1 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 2.5 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

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

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

Species: Rat

Application Route: Oral

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

weight

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

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

based on animal experiments.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

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:



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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: Test Type: Embryo-foetal development

ment

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, Central nervous system, Gastrointestinal tract, Lungs) through prolonged or repeated exposure.

Product:

Target Organs : Cardio-vascular system, Central nervous system, Gastrointes-

tinal tract, Lungs

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Components:

Dorzolamide:

Target Organs : Central nervous system, Gastrointestinal tract, Bone, Blood,

Bladder

Assessment : May cause damage to organs through prolonged or repeated

exposure.

(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:

Dorzolamide:

Species : Rat NOAEL : 0.05 mg/kg

Application Route : Oral

Target Organs : Bladder, Kidney



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Species : Dog
NOAEL : 0.05 mg/kg
LOAEL : 2 mg/kg
Application Route : Oral
Exposure time : 1 yr

Target Organs : Gastrointestinal tract, Bone, Blood

Species : Monkey
NOAEL : 0.05 mg/kg

Exposure time : 1 yr

Target Organs : Gastrointestinal tract, Bone, Blood

(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:

Eye contact : Symptoms: The most common side effects are:, bitter taste,

burning or stinging of the eye, Blurred vision, Abdominal pain, Dizziness, digestive disorder, eye pain, Headache, hyperten-

sion, Nausea, upper respiratory tract infection



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Components:

Dorzolamide:

Eye contact : Symptoms: burning or stinging of the eye, Blurred vision, tear-

ing, asthenia, bitter taste, Nausea, dry mouth, Headache

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

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

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

libido, hair loss, Allergic reactions

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

trointestinal discomfort, Allergic reactions, Rash, hair loss,

altered mental status, Dizziness, changes in libido

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Dorzolamide:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 699 mg/l

Exposure time: 48 h

Toxicity to microorganisms : EC50 (Natural microorganism): > 800 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

(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

Benzododecinium chloride:



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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)

Toxicity to fish (Chronic tox-

icity)

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

mg/l

10

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)): > 0.001 - 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



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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

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:

Dorzolamide:

Biodegradability : Result: not rapidly degradable

: 1

Biodegradation: 5 % Exposure time: 28 d

Method: OECD Test Guideline 314

(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

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:

Dorzolamide:



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Partition coefficient: n-

: log Pow: 0.292

octanol/water

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

Partition coefficient: n- : log Pow: 1.48

octanol/water

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

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

Environmentally hazardous : no



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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

Not applicable UN number Proper shipping name : Not applicable : Not applicable Class : 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.

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

i nonly recomment comments				
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



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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

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

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

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



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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

Sources of key data used to : compile the Safety Data Sheet

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

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

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

Date format : 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



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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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