

**Timolol / Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
11.1	2025/04/14	28813-00026	Date of first issue: 2014/11/06

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**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

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**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, Central nervous system, Gastrointestinal tract, 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.

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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	$\geq 1 - < 10$	-
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	$\geq 0.1 - < 1$	-
Benzododecinium chloride	139-07-1	$\geq 0.0025 - < 0.025$	3-2694 / 1-215, 1-215 / 3-326
Miristalkonium chloride	139-08-2	$\geq 0.0025 - < 0.025$	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).

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Notes to physician : Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides  
Hydrogen chloride
- 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 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 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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>Store in accordance with the particular national regulations. |
| Materials to avoid          | : | Do not store with the following product types:<br>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 / Concentration standard /	Basis
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			Permissible concentration	
Dorzolamide	130693-82-2	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Eye				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Eye, Skin				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**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 containment devices).  
 Minimize open handling.

**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** : 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, disposable 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 / 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	:	5.6
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	:	
Relative density	:	1.02
Density	:	No data available
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.

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.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
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                                      : Rabbit  
Method                                        : Draize Test  
Result                                         : 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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**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 - Assessment : Weight of evidence does not support classification as a carcinogen

**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 development : 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 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.

**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:**

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

**Product:**

Target Organs : Cardio-vascular system, Central nervous system, Gastrointestinal 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, hypertension, Nausea, upper respiratory tract infection
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**Components:****Dorzolamide:**

Eye contact : Symptoms: burning or stinging of the eye, Blurred vision, tearing, 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, Gastrointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido

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**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 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

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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 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

**Persistence and degradability****Components:****Dorzolamide:**

Biodegradability : Result: not rapidly degradable  
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-octanol/water : log Pow: 0.292

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

Partition coefficient: n-octanol/water : log Pow: 1.48

**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 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  
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 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

**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

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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 (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

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

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

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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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