

Dorzolamide Formulation

Version 9.1 Revision Date: 2025/04/14 SDS Number: 28990-00025 Date of last issue: 2024/09/28
Date of first issue: 2014/11/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : 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**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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	$\geq 1 - < 10$	-
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

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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 if symptoms occur.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty of water. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO _x) 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.

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6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE**Handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.

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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 (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Dorzolamide	130693-82-2	TWA	10 µg/m ³ (OEB 3)	Internal
	Further information: Eye			
		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 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,

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		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.

Physical state	:	Aqueous solution
Colour	:	No data available
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	:	No data available
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	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	soluble

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

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Not classified based on available information.

Product:

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

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:**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

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

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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

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:**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.

Species : Mouse
Application Route : Oral
Exposure time : 21 month(s)
Result : negative

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

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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 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

Benzododecinium chloride:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials

Miristalkonium chloride:

Effects on fertility	:	Test Type: Two-generation study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416
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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

Not classified based on available information.

Components:**Dorzolamide:**

Target Organs : Central nervous system, Gastrointestinal tract, Bone, Blood, Bladder
Assessment : May cause 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

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

Benzododecinium chloride:

Species : Rat
NOAEL : > 25 mg/kg
Application Route : Ingestion
Exposure time : 52 Weeks

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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**Components:****Dorzolamide:**

Eye contact : Symptoms: burning or stinging of the eye, Blurred vision, tearing, asthenia, bitter taste, Nausea, dry mouth, Headache

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

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

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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

Miristakonium chloride:

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

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

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

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

M-Factor (Acute aquatic toxicity) : 10

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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

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:**

Partition coefficient: n-octanol/water : log Pow: 0.292

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

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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

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

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

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

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

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

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

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

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

Not applicable

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

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

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

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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

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 Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SAFETY DATA SHEET



Dorzolamide Formulation

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