

Dorzolamide Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.8 30.09.2023 28992-00020 Date of first issue: 07.11.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dorzolamide Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Specific target organ toxicity : Category 2 (Central nervous system, Gastrointestinal tract,

- repeated exposure Bone, Blood, Bladder)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Central nervous system,

Gastrointestinal tract, Bone, Blood, Bladder) through prolonged

or repeated exposure.

Precautionary Statements : Prevention:

P260 Do not breathe mist or vapors.

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components



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Chemical name	CAS-No.	Concentration (% w/w)	
Dorzolamide	130693-82-2	>= 1 -< 5	

SECTION 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

May cause damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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)

Sulfur 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

80.

Evacuate area.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES



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Personal precautions, protective equipment and emer-

gency 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 diking or other appropriate

containment to keep material from spreading. If diked material

can be pumped, store recovered material in appropriate container.

onianiei.

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.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Advice on safe handling

Use only with adequate ventilation.

Do not breathe mist or vapors.

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.

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.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents



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Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Dorzolamide	130693-82-2	TWA	10 μg/m3 (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,

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Color : No data available



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Odor : No data available

Odor Threshold : No data available

pH : 5.6

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : Not applicable

Particle size : Not applicable



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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 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: > 5,000 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

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Dorzolamide:

Species : Monkey

Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.



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Respiratory sensitization

Not classified based on available information.

Components:

Dorzolamide:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : Weak sensitizer

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

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 hu-

mans.

Species : Mouse Application Route : Oral

Exposure time : 21 month(s)
Result : negative



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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 fetal 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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Central nervous system, Gastrointestinal tract, Bone, Blood, Bladder) 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.

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



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Exposure time : 1 y

Target Organs : Gastrointestinal tract, Bone, Blood

Species : Monkey NOAEL : 0.05 mg/kg

Exposure time : 1 y

Target Organs : Gastrointestinal tract, Bone, Blood

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, tear-

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

SECTION 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

Persistence and degradability

Components:

Dorzolamide:

Biodegradability : Result: not rapidly degradable

Biodegradation: 5 % Exposure time: 28 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Dorzolamide:

Partition coefficient: n-

octanol/water

log Pow: 0.292



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Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

: Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined



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SECTION 16. OTHER INFORMATION

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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation. Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8