

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Dorzolamide Formulation

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

**1.3 Details of the supplier of the safety data sheet**

Company : MSD  
117 16th Road  
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

**1.4 Emergency telephone number**

+1-908-423-6000

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**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

**2.2 Label elements**

**Labelling (REGULATION (EC) No 1272/2008)**

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

**Additional Labelling**

EUH210 Safety data sheet available on request.

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Dorzolamide	130693-82-2	Acute Tox. 4; H302 STOT RE 2; H373 (Central nervous system, Gastroin- testinal tract, Bone, Blood, Bladder)	>= 1 - < 10

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures****4.1 Description of 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.
- 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).
- 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.

**4.2 Most important symptoms and effects, both acute and delayed**

None known.

**4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically and supportively.

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

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

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**6.2 Environmental precautions**

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.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate contain-

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

ment 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.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe 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>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>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.<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. |

**7.2 Conditions for safe storage, including any incompatibilities**

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Gases                  |

**7.3 Specific end use(s)**

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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

**8.2 Exposure controls****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**

Eye/face 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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
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 (P)

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

Odour 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
Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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.

**9.2 Other information**

Molecular weight	:	Not applicable
Particle size	:	Not applicable

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

---

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

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

Species	:	Monkey
Result	:	Mild eye irritation

**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

**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



**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

Result	: 20 mg/kg body weight
Remarks	: negative
	: The mechanism or mode of action may not be relevant in humans.

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

**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

**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:**

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

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

**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

**SECTION 12: Ecological information****12.1 Toxicity****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

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

Biodegradability : Result: not rapidly degradable  
Biodegradation: 5 %  
Exposure time: 28 d

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

Method: OECD Test Guideline 314

**12.3 Bioaccumulative potential****Components:****Dorzolamide:**

Partition coefficient: n-octanol/water : log Pow: 0,292

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

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**SECTION 14: Transport information****14.1 UN number**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

---

**IATA** : Not regulated as a dangerous good

**14.2 UN proper shipping name**

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

**14.4 Packing group**

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

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

**Full text of H-Statements**

H302 : Harmful if swallowed.  
H373 : May cause damage to organs through prolonged or repeated exposure.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

**Further information**

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

**Dorzolamide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
1.22	14.04.2025	29002-00023	Date of first issue: 07.11.2014

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