

**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 |

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**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

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**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 disposal plant.

**Other hazards**

None known.

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**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 (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>)  
Sulfur 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 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 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 diking or other appropriate containment to keep material from spreading. If diked 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.

**SECTION 7. HANDLING AND STORAGE**

- 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 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<br>(Form of exposure) | Control parameters / Permissible concentration | 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 |

**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 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. |

**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<br>Method: Calculation method |
|---------------------|---|----------------------------------------------------------------------|

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

|                           |   |                                                      |
|---------------------------|---|------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 1,927 mg/kg<br>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<br>Result: negative                                                                 |
|                       |   | Test Type: Alkaline elution assay<br>Test system: rat hepatocytes<br>Result: negative                                 |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Test system: Chinese hamster fibroblasts<br>Result: negative |
|                       |   | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                |
| Genotoxicity in vivo  | : | Test Type: Cytogenetic assay<br>Species: Mouse<br>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 humans. |
| 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<br>Species: Rat, male and female<br>Application Route: Oral<br>Fertility: NOAEL: 7.5 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility.                                                                                                                                                                                                                                                                                                               |
| Effects on fetal development | : | Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 1 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 2.5 mg/kg body weight<br>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, tearing, 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 : 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

**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- : log Pow: 0.292  
octanol/water

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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.<br>Dispose of in accordance with local regulations.                                                                     |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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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Date format : dd.mm.yyyy

**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

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