

## SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 04-Jun-2025 Revision Number 2

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Code(s) CAT 1069

Product Name dorzolamide hydrochloride

Form Not applicable

REACH registration number

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

Substance Name Dorzolamide Hydrochloride

EC No (EU Index No) 620-304-2

**CAS No.** 130693-82-2

Pure substance/mixture Substance

**Formula** C10 H16 N2 O4 S3 . H Cl

Molecular weight 360.9

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

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#### **Supplier**

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

For further information, please contact

E-mail address bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

| Emergency Telephone - §45 - (EC)1272/2008 |                          |  |  |  |
|---|--------------------------|--|--|--|
| Europe                                    | 112                      |  |  |  |
| Austria                                   | No information available |  |  |  |
| Bulgaria                                  |                          |  |  |  |
| Croatia                                   |                          |  |  |  |
| Cyprus                                    |                          |  |  |  |
| Czech Republic                            |                          |  |  |  |
| Denmark                                   |                          |  |  |  |
| France                                    |                          |  |  |  |
| Hungary                                   |                          |  |  |  |
| Ireland                                   |                          |  |  |  |
| Italy                                     |                          |  |  |  |
| Lithuania                                 |                          |  |  |  |
| Luxembourg                                |                          |  |  |  |
| Netherlands                               |                          |  |  |  |
| Norway                                    |                          |  |  |  |
| Portugal                                  |                          |  |  |  |
| Romania                                   |                          |  |  |  |
| Slovakia                                  |                          |  |  |  |
| Slovenia                                  |                          |  |  |  |
| Spain                                     |                          |  |  |  |

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| Sweden      |  |
|-------------|--|
| Switzerland |  |

### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Oral Category 4 - (H302)

Eye irritationCategory 2 - (H319)Specific target organ toxicity (repeated exposure)Category 2 - (H373)

### 2.2. Label elements

Contains Dorzolamide Hydrochloride





Signal word Warning

#### **Hazard statements**

H302 - Harmful if swallowed.

H319 - Causes serious eye irritation.

H373 - May cause damage to organs through prolonged or repeated exposure.

#### Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear eye and face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable P337 + P313 - If eye irritation persists: Get medical advice/attention

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#### 2.3. Other hazards

No information available.

PBT & vPvB

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

EU - REACH (1907/2006) - Article 59(1)
- Candidate List of Substances of Very
High Concern (SVHC) for Authorisation

Dorzolamide Hydrochloride

This product does not contain any known or suspected endocrine disruptors.

EU - REACH (1907/2006) - Endocrine
Disruptor Assessment List of
Substances

-

## SECTION 3: Composition/information on ingredients

#### 3.1 Substances

| Chemical name | Weight-% | REACH        | EC No (EU | Classification      | Specific      | M-Factor | M-Factor  | Notes |
|---------------|----------|--------------|-----------|---------------------|---------------|----------|-----------|-------|
|               |          | registration | Index No) | 9                   | concentration |          | (long-ter |       |
|               |          | number       |           | Regulation (EC) No. | limit (SCL)   |          | m)        |       |
|               |          |              |           | 1272/2008 [CLP]     |               |          |           |       |
| Dorzolamide   | 100      | -            | 620-304-2 | Acute Tox. 4 (H302) | -             | -        | -         | -     |
| Hydrochloride |          |              |           | Eye Irrit. 2 (H319) |               |          |           |       |
| 130693-82-2   |          |              |           | STOT RE 2 (H373)    |               |          |           |       |
|               |          |              |           |                     |               |          |           |       |

#### Full text of H- and EUH-phrases: see section 16

#### **Acute Toxicity Estimate**

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

| Chemical name                               | Oral LD50 mg/kg | Dermal LD50       | Inhalation LC50 - 4     | Inhalation LC50 - 4  | Inhalation LC50 - 4 |
|---|-----------------|-------------------|-------------------------|----------------------|---------------------|
|   |                 | mg/kg             | hour - dust/mist - mg/L | hour - vapour - mg/L | hour - gas - ppm    |
| Dorzolamide<br>Hydrochloride<br>130693-82-2 | 1927            | No data available | No data available       | No data available    | No data available   |

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This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

**Skin contact**Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

doctor.

**Ingestion** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Call a doctor.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms** May cause redness and tearing of the eyes. Burning sensation.

**Effects of Exposure** May cause damage to organs through prolonged or repeated exposure.

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

**Note to doctors**Treat symptomatically.

### SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

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Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

## **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions**Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

#### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children.

Storage class (TRGS 510) LGK 11.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

#### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure

limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers No information available

Derived No Effect Level (DNEL) - General Public No information available.

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Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are Eye/face protection

likely to occur, wear safety glasses with side-shields.

Wear suitable gloves. The protective gloves to be used must comply with the specifications Hand protection

of EC Directive 89/686/EEC and the related standard EN374.

**Gloves** 

**Duration of contact** Glove thickness Break through time PPE - Glove material 0.11 mm 480 minutes Wear protective nitrile rubber

gloves

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

Do not allow into any sewer, on the ground or into any body of water. **Environmental exposure controls** 

#### SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

**Appearance** Solid Physical state Solid

Colour white, to, off-white Odour No information available **Odour threshold** No information available

Remarks • Method **Property Values** 

Melting point / freezing point 260 - 270 °C None known

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Initial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known No data available **Autoignition temperature** None known **Decomposition temperature** None known None known No data available SADT (°C) No data available None known pН pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known Water solubility Soluble in water None known

Solubility(ies) slightly soluble Ethanol Methanol

Partition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density

Relative variety

No data available

No data available

No data available

Relative vapour density No data available None known

**Particle characteristics** 

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

Molecular formula C10 H16 N2 O4 S3 . H CI

Molecular weight 360.9

#### 9.2.1. Information with regards to physical hazard classes

No information available

#### 9.2.2. Other safety characteristics

No information available

### SECTION 10: Stability and reactivity

10.1. Reactivity

**Reactivity** No information available.

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10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions 
None under normal processing.

10.4. Conditions to avoid

**Conditions to avoid**None known based on information supplied.

10.5. Incompatible materials

**Incompatible materials**None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

### SECTION 11: Toxicological information

# 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on likely routes of exposure

**Inhalation** Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** May cause redness and tearing of the eyes.

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Dermal LD50

Inhalation LC50

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Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Acute toxicity** 

Harmful if swallowed.

Oral LD50

Numerical measures of toxicity

Chemical name

|                                   | Dorzolamide Hydrochloride | = 1927 mg/kg (Rat)              | -                                 | -                         |
|-----------------------------------|---------------------------|---------------------------------|-----------------------------------|---------------------------|
|                                   | Skin corrosion/irritation | Based on available data, the cl | assification criteria are not met | t.                        |
| Serious eye damage/eye irritation |                           | Classification based on data av | /ailable for ingredients. Causes  | s serious eye irritation. |
| Respiratory or skin sensitisation |                           | Based on available data, the cl | assification criteria are not met | t.                        |

| Germ cell mutagenicity | Based on available data, the classification criteria are not met. |  |
|------------------------|---|--|
|                        |   |  |

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

**STOT - single exposure**Based on available data, the classification criteria are not met.

**STOT - repeated exposure** May cause damage to organs through prolonged or repeated exposure.

**Aspiration hazard** Based on available data, the classification criteria are not met.

11.2. Information on other hazards

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11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

**PMT or vPvM properties**Based on available data, the classification criteria are not met.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

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### **SECTION 14: Transport information**

| IATA |
|------|
|------|

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

#### **IMDG**

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions

14.7 Maritime transport in bulk No information available according to IMO instruments

#### RID

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

#### ADR

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

<u>ADN</u>

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14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazard
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

### SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK)
Chemical Prohibition Ordinance

(ChemVerbotsV)

slightly hazardous to water (WGK 1)

Not applicable

TRGS 905 Not applicable

### **Switzerland**

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018
Storage of Hazardous Material
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20
Major Accidents Ordinance SR 814.012
Not applicable

#### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

## DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

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#### **Persistent Organic Pollutants**

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 2024/590

Not applicable

#### **International Inventories**

TSCA LGC has not confirmed that the chemical substances in this product are on the TSCA

Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided

at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the

requirements that apply to its use of this product.
Contact supplier for inventory compliance status

KECLContact supplier for inventory compliance statusPICCSContact supplier for inventory compliance statusAIICContact supplier for inventory compliance status

#### Legend:

DSL/NDSL

**ENCS** 

**IECSC** 

**EINECS/ELINCS** 

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

#### 15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

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### **SECTION 16: Other information**

#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H302 - Harmful if swallowed

H319 - Causes serious eye irritation

H373 - May cause damage to organs through prolonged or repeated exposure

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P314 - Get medical advice/attention if you feel unwell

| egend |  |
|-------|--|
|       |  |

| Logona    |   |
|-----------|---|
| ACGIH     | American Conference of Governmental Industrial Hygienists                                       |
| AIDII     | Italian Association of Industrial Hygienists  |
| ADN       | Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe) |
| ADR       | Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)             |
| AIIC      | Australian Inventory of Industrial Chemicals  |
| ATE       | Acute Toxicity Estimate   |
| ASTM      | American Society for the Testing of Materials   |
| bar       | Biological Reference Values for Chemical Compounds in the Work Area                             |
| BAT       | Biological tolerance values for occupational exposure   |
| BEL       | Biological exposure limits  |
| bw        | Body weight   |
| Ceiling   | Maximum limit value   |
| CLP       | Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008                |
| CMR       | Carcinogen, Mutagen or Reproductive Toxicant  |
| DFG       | German Research Foundation  |
| DOT       | Department of Transportation (United States)  |
| DSL       | Domestic Substances List (Canada)   |
| ECHA      | European Chemicals Agency   |
| EC Number | European Community number   |
|           |   |

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| EmS     | Emergency Schedule  |  |  |
|---------|---|--|--|
| ENCS    | Existing and New Chemical Substances (Japan)  |  |  |
| EPA     | Environmental Protection Agency   |  |  |
| EWC     | European Waste Codes  |  |  |
| GHS     | Globally Harmonized System  |  |  |
| 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   |  |  |
| ICAO    | International Civil Aviation Organisation   |  |  |
| IECSC   | Inventory of Existing Chemical Substances in China  |  |  |
| IMDG    | International Maritime Dangerous Goods  |  |  |
| IMO     | International Maritime Organization   |  |  |
| ISO     | International Organisation for Standardisation  |  |  |
| KECI    | Korean Existing Chemicals Inventory   |  |  |
| LC50    | Lethal Concentration to 50% of a test population  |  |  |
| LD50    | Lethal Dose to 50% of a test population (Median Lethal Dose)  |  |  |
| MAL     | Measuring Technical Hygienic Air Needs  |  |  |
| MARPOL  | International Convention for the Prevention of Pollution from Ships                                     |  |  |
| MDLPS   | Ministry of Labour and Social Policy  |  |  |
| n.o.s.  | Not Otherwise Specified   |  |  |
| NOAEC   | No Observed Adverse Effect Concentration  |  |  |
| NOAEL   | No Observed Adverse Effect Level  |  |  |
| NOELR   | No Observable Effect Loading Rate   |  |  |
| NZIoC   | New Zealand Inventory of Chemicals  |  |  |
| OECD    | Organization for Economic Cooperation and Development   |  |  |
| OEL     | Occupational exposure limits  |  |  |
| PBT     | Persistent, Bioaccumulative and Toxic substance   |  |  |
| PICCS   | Philippines Inventory of Chemicals and Chemical Substances  |  |  |
| PMT     | Persistent, Mobile and Toxic  |  |  |
| PPE     | Personal protective equipment   |  |  |
| QSAR    | Quantitative Structure Activity Relationship  |  |  |
| REACH   | Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006) |  |  |
| RID     | Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)                     |  |  |
| SADT    | Self-Accelerating Decomposition Temperature   |  |  |
| SAR     | Structure-activity relationship   |  |  |
| SDS     | Safety Data Sheet   |  |  |
| SL      | Surface Limit   |  |  |
| STEL    | Short Term Exposure Limit   |  |  |
| STOT RE | Specific target organ toxicity - Repeated exposure  |  |  |

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# SAFETY DATA SHEET

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#### CAT 1069 - dorzolamide hydrochloride

| STOT SE | Specific target organ toxicity - Single exposure |                            |  |
|---------|--|----------------------------|--|
| SVHC    | Substance of very high concern                   |                            |  |
| TCSI    | Taiwan Chemical Substance Inventory              |                            |  |
| TDG     | Transport of Dangerous Goods (Canada)            |                            |  |
| TRGS    | Technical Rule for Hazardous Substances          |                            |  |
| TSCA    | Toxic Substances Control Act (United States)     |                            |  |
| TWA     | Time-Weighted Average                            |                            |  |
| UN      | United Nations                                   |                            |  |
| VOC     | Volatile organic compounds                       | Volatile organic compounds |  |
| vPvB    | Very Persistent and Very Bioaccumulative         |                            |  |
| vPvM    | Very Persistent and Very Mobile                  |                            |  |
| Sen+    | Sensitiser                                       |                            |  |
| Sk*     | Skin designation                                 | Skin designation           |  |
| **      | Hazard Designation                               |                            |  |

| Classification procedure  |                    |  |  |  |
|---|--------------------|--|--|--|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used        |  |  |  |
| Acute oral toxicity   | Calculation method |  |  |  |
| Acute dermal toxicity   | Calculation method |  |  |  |
| Acute inhalation toxicity - gas                                 | Calculation method |  |  |  |
| Acute inhalation toxicity - vapour                              | Calculation method |  |  |  |
| Acute inhalation toxicity - dust/mist                           | Calculation method |  |  |  |
| Skin corrosion/irritation                                       | Calculation method |  |  |  |
| Serious eye damage/eye irritation                               | Calculation method |  |  |  |
| Respiratory sensitisation                                       | Calculation method |  |  |  |
| Skin sensitisation  | Calculation method |  |  |  |
| Mutagenicity  | Calculation method |  |  |  |
| Carcinogenicity   | Calculation method |  |  |  |
| Reproductive toxicity   | Calculation method |  |  |  |
| STOT - single exposure  | Calculation method |  |  |  |
| STOT - repeated exposure  | Calculation method |  |  |  |
| Chronic aquatic toxicity  | Calculation method |  |  |  |
| Acute aquatic toxicity  | Calculation method |  |  |  |
| Aspiration hazard   | Calculation method |  |  |  |
| Ozone   | Calculation method |  |  |  |

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

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European Chemicals Agency (ECHA) (ECHA\_API)

**Environmental Protection Agency** 

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

### **Revision date**

04-Jun-2025

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

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**End of Safety Data Sheet** 

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