

Dorzolamide impurity A

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 31/01/2023 Revision date: 05/06/2026 Supersedes version of: 03/03/2025 Version: 3.0

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

1.1. Product identifier

Product form : Substance
Substance name : Dorzolamide impurity A
Chemical name : (4R,6R)-4-(Ethylamino)-6-methyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-2-sulfonamide 7,7-dioxide
CAS-No. : 120279-95-0
Product code : 202200440

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

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
Skin sensitisation, Category 1 H317
Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

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

Hazard pictograms (CLP) :  
GHS07 GHS08

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.
H317 - May cause an allergic skin reaction.

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Precautionary statements (CLP)

- H373 - May cause damage to organs (central nervous system, blood, urinary system) through prolonged or repeated exposure.
- : P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P272 - Contaminated work clothing should not be allowed out of the workplace.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
- P302+P352 - IF ON SKIN: Wash with plenty of water.
- P314 - Get medical advice/attention if you feel unwell.
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- P330 - Rinse mouth.
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)



2.3. Other hazards

Other information

- : Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
(4R,6R)-4-(Ethylamino)-6-methyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-2-sulfonamide 7,7-dioxide	CAS-No.: 120279-95-0	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg) Skin Sens. 1, H317 STOT RE 2, H373

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

- Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- | | |
|--------------------------------|---|
| Suitable extinguishing media | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

- | | |
|--|--|
| Hazardous decomposition products in case of fire | : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released. |
|--|--|

5.3. Advice for firefighters

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|--------------------------------|--|
| Firefighting instructions | : Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- | | |
|------------------|---|
| General measures | : Avoid contact with skin, eyes and clothing. |
|------------------|---|

For non-emergency personnel

- | | |
|----------------------|-----------------------------------|
| Emergency procedures | : Evacuate unnecessary personnel. |
|----------------------|-----------------------------------|

For emergency responders

- | | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- | | |
|-------------------------|---|
| For containment | : Absorb with an inert material and place in an appropriate waste disposal container. |
| Methods for cleaning up | : Clean contaminated surfaces with an excess of water. Clean with the help of detergents. |

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- | | |
|-------------------------------|--|
| Precautions for safe handling | : Avoid all unnecessary exposure. Ensure good ventilation of the work station. |
| Hygiene measures | : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work. |

7.2. Conditions for safe storage, including any incompatibilities

- | | |
|---------------------|---|
| Storage conditions | : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight. |
| Packaging materials | : Keep in original containers. |

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Molecular mass	: 324,4 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: $\approx 284\text{ }^{\circ}\text{C}$
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

(4R,6R)-4-(Ethylamino)-6-methyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-2-sulfonamide 7,7-dioxide (120279-95-0)	
LD50 oral rat	> 300 – ≤ 2000 mg/kg (estimated value)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: May cause damage to organs (central nervous system, blood, urinary system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

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12.2. Persistence and degradability

(4R,6R)-4-(Ethylamino)-6-methyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-2-sulfonamide 7,7-dioxide (120279-95-0)

Persistence and degradability

Not rapidly degradable

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

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Air transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Modified
	Revision date	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Precautionary statements (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
4.1	First-aid measures after skin contact	Modified
4.2	Symptoms/effects after skin contact	Added
9	Molecular mass	Added
9	Melting point	Added
11.1	ATE CLP (oral)	Added
11.1	LD50 oral rat	Modified

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Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H373	May cause damage to organs (central nervous system, blood, urinary system) through prolonged or repeated exposure.

Safety Data Sheet (SDS), EU

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