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

1.1. Product identifier

Product form : Substance
Substance name : Acetazolamide
Product code : 201600010
Synonyms : Acetazolamide, salts, hydrates, isomers and impurities where applicable
Other means of identification : Ph.Eur. 0454

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

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
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)380215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
- Skin corrosion/irritation, Category 2 : H315
- Serious eye damage/eye irritation, Category 2 : H319
- Reproductive toxicity, Category 1B : H360D

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects
Expert judgement and weight of evidence determination.

2.2. Label elements

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

Hazard pictograms (CLP) : 

Signal word (CLP) : Danger
Hazard statements (CLP) : H315 - Causes skin irritation.
                        H319 - Causes serious eye irritation.
                        H360D - May damage the unborn child.
Acetazolamide
Safety Data Sheet
Safety Data Sheet in accordance with regulation (EC) No 1907/2006, as amended.

Precautionary statements (CLP):

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P302+P352 - IF ON SKIN: Wash with plenty of water.
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- P332+P313 - If skin irritation occurs: Get medical advice/attention.
- P337+P313 - If eye irritation persists: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.
- P405 - Store locked up.
- 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): GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
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<tbody>
<tr>
<td>Acetazolamide</td>
<td></td>
<td>≤ 100</td>
<td>Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 1B, H360D</td>
</tr>
</tbody>
</table>

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation: Move to fresh air. Allow affected person to breathe fresh air.
- First-aid measures after skin contact: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
- First-aid measures after eye contact: Rinse with water while holding the eyes wide open.
- First-aid measures after ingestion: Rinse mouth. Specific medical surveillance. Prolonged medical observation may be indicated.

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

- Symptoms/effects: Delayed adverse effects possible.
- Symptoms/effects after inhalation: Insufficient data available.
- Symptoms/effects after skin contact: Insufficient data available.
- Symptoms/effects after eye contact: Insufficient data available.
- Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination.
4.3. Indication of any immediate medical attention and special treatment needed
Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media : Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture
Fire hazard : See Heading 2.2.

5.3. Advice for firefighters
Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. For non-emergency personnel
Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

6.1.2. For emergency responders
No additional information available

6.2. Environmental precautions
No additional information available

6.3. Methods and material for containment and cleaning up
Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

6.4. Reference to other sections
No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities
Technical measures : Comply with applicable regulations.
Storage conditions : Store locked up.

7.3. Specific end use(s)
See Heading 1.
SECTION 8: Exposure controls/personal protection

8.1. Control parameters
No additional information available

8.2. Exposure controls

Appropriate engineering controls:
Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

Hand protection:
Chemically resistant protective gloves. EN 374

Eye protection:
Safety glasses. DIN EN 166

Skin and body protection:
Use chemically protective clothing. DIN EN 13034

Respiratory protection:
Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product: Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
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<td>Colour</td>
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</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour threshold</td>
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</tr>
<tr>
<td>pH</td>
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<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
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</tr>
<tr>
<td>Melting point</td>
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</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
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</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Water: 0.1 – 1 g/l</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Pow)</td>
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</tr>
<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Viscosity, dynamic</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidising properties</td>
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<tr>
<td>Explosive limits</td>
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</table>

9.2. Other information
No additional information available
Acetazolamide
Safety Data Sheet

SECTION 10: Stability and reactivity

10.1. Reactivity
Stable under normal conditions.

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
None under normal use. See Heading 7.

10.6. Hazardous decomposition products
When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| Acute toxicity (oral)          | Not classified (Lack of data) |
| Acute toxicity (dermal)       | Not classified (Lack of data)  |
| Acute toxicity (inhalation)   | Not classified (Lack of data)  |

**Acetazolamide**

LD50 oral rat: > 2000 mg/kg

- Skin corrosion/irritation: Causes skin irritation.
- Serious eye damage/irritation: Causes serious eye irritation. (Lack of data)
- Respiratory or skin sensitisation: Not classified (Based on available data, the classification criteria are not met)
- Germ cell mutagenicity: Not classified (Lack of data)
- Carcinogenicity: Not classified (Lack of data)
- Reproductive toxicity: May damage the unborn child.
- STOT-single exposure: Not classified (Lack of data)
- STOT-repeated exposure: Not classified (Lack of data)
- Aspiration hazard: Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

- Ecology - general: Hazardous waste. Use suitable disposal containers.
- Hazardous to the aquatic environment, short-term (acute): Not classified
- Hazardous to the aquatic environment, long-term (chronic): Not classified

12.2. Persistence and degradability
No additional information available
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. Other adverse effects
No additional information available

SECTION 13: Disposal considerations
13.1. Waste treatment methods
Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information
In accordance with ADR / IATA / IMDG

<table>
<thead>
<tr>
<th></th>
<th>ADR</th>
<th>IMDG</th>
<th>IATA</th>
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<td>Not applicable</td>
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<tr>
<td>14.2. UN proper shipping name</td>
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<td>Not applicable</td>
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<tr>
<td>14.3. Transport hazard class(es)</td>
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<td>Not applicable</td>
<td>Not applicable</td>
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<tr>
<td>14.4. Packing group</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

No supplementary information available

14.6. Special precautions for user
Overland transport
Not applicable
Transport by sea
Not applicable
Air transport
Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable

SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
15.1.1. EU-Regulations
No REACH Annex XVII restrictions
**Acetazolamide**

Safety Data Sheet in accordance with regulation (EC) No 1907/2006, as amended.

Acetazolamide is not on the REACH Candidate List
Acetazolamide is not on the REACH Annex XIV List

**15.1.2. National regulations**

No additional information available

**15.2. Chemical safety assessment**

No additional information available

**SECTION 16: Other information**

<table>
<thead>
<tr>
<th>Indication of changes:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section</strong></td>
</tr>
<tr>
<td>2</td>
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<td>2</td>
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<td>2</td>
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</table>

<table>
<thead>
<tr>
<th>Full text of H- and EUH-statements:</th>
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</thead>
<tbody>
<tr>
<td><strong>Eye Irrit. 2</strong></td>
</tr>
<tr>
<td><strong>Repr. 1B</strong></td>
</tr>
<tr>
<td><strong>Skin Irrit. 2</strong></td>
</tr>
<tr>
<td><strong>H315</strong></td>
</tr>
<tr>
<td><strong>H319</strong></td>
</tr>
<tr>
<td><strong>H360D</strong></td>
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**DISCLAIMER OF LIABILITY**

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