

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

1.1. Product identifier

Product form : Substance
Substance name : Captopril
Product code : 201600143
Synonyms : Captopril, salts, hydrates, isomers and impurities where applicable

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
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]

Skin sensitisation, Category 1 H317
Reproductive toxicity, Category 1A H360
Full text of H- and EUH-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) : H317 - May cause an allergic skin reaction.
H360 - May damage fertility or the unborn child.
Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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P302+P352 - IF ON SKIN: Wash with plenty of water.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: 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

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------|--------------------|-------|---|
| Captopril | - | ≤ 100 | Skin Sens. 1, H317 Repr. 1A, H360 |

Full text of H- and EUH-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 substance. Pharmaceutical.

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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

8.1.1 National occupational exposure and biological limit values

No additional information available

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8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering 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).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

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

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---------------------------|-------------------|
| Physical state | : Solid |
| Colour | : Not available |
| Odour | : Not applicable. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not available |
| Boiling point | : Not available |
| Flammability | : Not available |
| Explosive limits | : Not applicable |
| 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 |

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| | |
|---|-------------------------|
| Solubility | : Water: 33.3 – 100 g/l |
| 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 |

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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 Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

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

| | |
|-----------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |

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| | |
|---------------|------------|
| LD50 oral rat | 4525 mg/kg |
|---------------|------------|

| | |
|-----------------------------------|---|
| 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 (Lack of data) |
| Carcinogenicity | : Not classified (Lack of data) |
| Reproductive toxicity | : May damage fertility or the unborn child. |
| STOT-single exposure | : Not classified (Lack of data) |
| STOT-repeated exposure | : Not classified (Lack of data) |
| Aspiration hazard | : Not classified (Technical impossibility to obtain the data) |

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11.2. Information on other hazards

No additional information available

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

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. 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

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR | IMDG | IATA |
|---|----------------|----------------|
| 14.1. UN number or ID number | | |
| Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | |
| Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | |
| Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | |
| Not applicable | Not applicable | Not applicable |

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| ADR | IMDG | IATA |
|--|----------------|----------------|
| 14.5. Environmental hazards | | |
| Not applicable | Not applicable | Not applicable |
| 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. 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

15.1.1. 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

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

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SECTION 16: Other information

Full text of H- and EUH-statements:

| | |
|--------------|---|
| H317 | May cause an allergic skin reaction. |
| H360 | May damage fertility or the unborn child. |
| Repr. 1A | Reproductive toxicity, Category 1A |
| Skin Sens. 1 | Skin sensitisation, Category 1 |

Safety Data Sheet (SDS), EU

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