

Page 1/8

#### Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

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

- · Product identifier
- Trade name: <u>Captopril, API</u>
- · Article number: 4155
- · CAS Number:
- 62571-86-2
- EC number:
- 263-607-1
- $\cdot$  Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture
- Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- · Uses advised against No relevant information available.
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier: CAELO Caesar & Loretz GmbH Herderstr. 31 D-40721 Hilden GERMANY
- Further information obtainable from: E-mail: info@caelo.de Tel.: +49210349940 (during regular opening hours)
   Emergency telephone number: Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn Tel: +49 (0) 228-192400

#### 2 Hazards identification

- · Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
   Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 1A H360 May damage fertility or the unborn child.

· Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- The substance is classified and labelled according to the CLP regulation.
- · Hazard pictograms





Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

Page 2/8

#### Trade name: Captopril, API

<b>O</b> !	(Contd. of page
-	vord Danger
	statements
	ay cause an allergic skin reaction.
	ay damage fertility or the unborn child.
· Precauti	ionary statements
P261	
P280	
P280	
	313 IF exposed or concerned: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
· Other ha	azards
· Results	of PBT and vPvB assessment
Results	
· PBT: No	t applicable.
• <b>PBT:</b> No • <b>vPvB:</b> N	
• PBT: No • vPvB: N • Determi	ot applicable. lot applicable. <b>nation of endocrine-disrupting properties</b> Not applicable.
• PBT: No • vPvB: N • Determi	lot applicable. Iot applicable.
PBT: No vPvB: N Determi 3 Compo	ot applicable. lot applicable. nation of endocrine-disrupting properties Not applicable. osition/information on ingredients nces
PBT: No vPvB: N Determi 3 Compo	ot applicable. lot applicable. nation of endocrine-disrupting properties Not applicable. osition/information on ingredients
PBT: No vPvB: N Determi 3 Compo Substan CAS No	ot applicable. lot applicable. nation of endocrine-disrupting properties Not applicable. osition/information on ingredients nces
PBT: No vPvB: N Determi 3 Compo Substan CAS No CAS: 62	ot applicable. lot applicable. nation of endocrine-disrupting properties Not applicable. osition/information on ingredients nces . Description

#### 4 First aid measures

#### · Description of first aid measures

- After inhalation: Bring the person out of the contaminated area to fresh air. Seek immediate medical advice.
- After skin contact: Take off contaminated
- Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing:
- Drink plenty of water.
- Call a doctor immediately. Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

#### **5** Firefighting measures

- · Extinguishing media
- Suitable extinguishing agents:
   All regular extinguishing media can be used.
   Use fire extinguishing methods suitable to surrounding conditions.



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.03.2023

#### Trade name: Captopril, API

- Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Nitrogen oxides (NOx) Sulfur oxide (SxOy) Advice for firefighters • Protective equipment: In case of fire wear suitable protective clothes and respiratory protection. · Additional information Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations. 6 Accidental release measures Personal precautions, protective equipment and emergency procedures Avoid formation of dust. Avoid contact with the substance. Environmental precautions: Do not allow to enter sewers/ surface or ground water. Methods and material for containment and cleaning up:
- Take up dry. Clean up with water. Dispose contaminated material as waste according to item 13. Reference to other sections See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment.

#### See Section 13 for disposal information.

#### 7 Handling and storage

- Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about fire and explosion protection: Avoid dust formation when handling larger quantities.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:
- Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Store receptacle in a well ventilated area.
- · Storage class: TRHS 510: 11 Combustible solids
- · Specific end use(s) No further relevant information available.

#### 8 Exposure controls/personal protection

- · Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. Immediately remove all soiled and contaminated clothing
- · Respiratory protection: Dust protection mask.

Revision: 22.03.2023

Page 3/8

(Contd. of page 2)

Version number 1.00

## · Special hazards arising from the substance or mixture



# Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

Page 4/8

#### Trade name: Captopril, API

	(Contd. of page 3
Hand protection Protective gloves	
· Material of gloves	
Rubber gloves	
Natural rubber, NR	anand on the motorial, but also on further marks of
The selection of the suitable gloves does not only de	
quality and varies from manufacturer to manufacture • Penetration time of glove material	51.
	y the manufacturer of the protective gloves and has to
be observed.	y the manufacturer of the protective gloves and has to
• Eye/face protection Safety glasses	
Body protection: Protective work clothing	
0 Physical and chamical properties	
9 Physical and chemical properties Information on basic physical and chemical prop	antias
· General Information	Jernes
· Physical state	Solid
· Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· Melting point/freezing point:	104–108 °C
· Boiling point or initial boiling point and boiling	104-108 C
•••••••••••••••••••••••••••••••••••••••	Undetermined.
range · Lower and upper explosion limit	Undetermined.
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	Not applicable.
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
Solubility	
· water:	Not determined.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
Relative density	Not determined.
· Vapour density	Not applicable.
Particle characteristics	Not determined
· Other information	
· Appearance:	
· Form:	Crystalline powder
· Important information on protection of health	- /
and environment, and on safety.	
• Auto-ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· · · · · · · · · · · · · · · · · · ·	(Contd. on page 5



Page 5/8

#### Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

#### Trade name: Captopril, API

		(Contd. of page 4)
Change in condition		
· Evaporation rate	Not applicable.	
Information with regard to physical hazard		
classes		
Explosives	Void	
	Void	
· Flammable gases	Void	
	Void	
· Aerosols	Void	
	Void	
· Oxidising gases	Void	
	Void	
· Gases under pressure	Void	
	Void	
· Flammable liquids	Void	
	Void	
· Flammable solids	Void	
	Void	
· Self-reactive substances and mixtures	Void	
	Void	
· Pyrophoric liquids	Void	
	Void	
· Pyrophoric solids	Void	
i jiophono condo	Void	
Self-heating substances and mixtures	Void	
	Void	
• Substances and mixtures, which emit flammal		
gases in contact with water	Void	
guess in contact main nator	Void	
· Oxidising liquids	Void	
	Void	
· Oxidising solids	Void	
	Void	
· Organic peroxides	Void	
organio poroxidoo	Void	
· Corrosive to metals	Void	
	Void	
· Desensitised explosives	Void	
	Void	

#### 10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

• Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

• Possibility of hazardous reactions Reacts with strong oxidising agents.

• Conditions to avoid No further relevant information available.



Page 6/8

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

(Contd. of page 5)

#### Trade name: Captopril, API

· Incompatible materials: No further relevant information available.

• Hazardous decomposition products: Carbon monoxide Carbon dioxide Nitrogen oxides (NOx)

Sulphur dioxide

#### **11 Toxicological information**

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

- Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:
- Oral LD50 4,245 mg/kg (rat)
- · Skin corrosion/irritation
- May cause skin irritation.

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

- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · 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 May damage fertility or the unborn child.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- Information on other hazards
- · Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · **Bioaccumulative potential** No further relevant information available.
- · Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.



#### Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

(Contd. of page 6)

Page 7/8

#### Trade name: Captopril, API

·	Other	adverse	effects
---	-------	---------	---------

· Additional ecological information:

#### · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

#### 13 Disposal considerations

#### · Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to local regulations.

#### 14 Transport information

14 Transport information		
<ul> <li>UN number or ID number</li> <li>ADR, IMDG, IATA</li> </ul>	Not subject to transport regulations. not regulated	
UN proper shipping name	C C	
· IMDG, IATA	not regulated	
<ul> <li>Transport hazard class(es)</li> </ul>		
· ADR, ADN, IMDG, IATA		
Class	not regulated	
<ul> <li>Packing group</li> </ul>		
· ADR, IMDG, IATA	not regulated	
<ul> <li>Environmental hazards:</li> </ul>	Not applicable.	
• Special precautions for user	Not applicable.	
• Maritime transport in bulk according to IMO		
instruments	Not applicable.	
· UN "Model Regulation":	not regulated	

#### 15 Regulatory information

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

· LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed

· REGULATION (EC) No 1907/2006 ANNEX XVII Not listed

 DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II Substance is not listed.

· National regulations:

- Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany) TRHS 510: 11 Combustible solids
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

(Contd. on page 8)

IE -



Page 8/8

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.03.2023

Version number 1.00

Revision: 22.03.2023

(Contd. of page 7)

#### Trade name: Captopril, API

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended. Reasons for alterations This version replaces all old versions. Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Skin Sens. 1: Skin sensitisation - Category 1 Repr. 1A: Reproductive toxicity - Category 1A IE -