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

Printing date 10.03.2023

Version number 1.00

Revision: 10.03.2023

# 1 Identification of the substance/mixture and of the company/undertaking · Product identifier

- · Product identifier
- · Trade name: Chininhydrochlorid Dihydrate, API
- · Article number: 2176
- · CAS Number:
- 6119-47-7
- EC number:
- 612-097-2
- $\cdot$  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.

- · 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

Acute Tox. 4 H302 Harmful if swallowed.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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

· Label elements

· Labelling according to Regulation (EC) No 1272/2008

- The substance is classified and labelled according to the CLP regulation.
- · Hazard pictograms





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### Trade name: Chininhydrochlorid Dihydrate, API

### · Signal word Danger

- · Hazard statements
- H302 Harmful if swallowed.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.

## · Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Determination of endocrine-disrupting properties Not applicable.

# **3** Composition/information on ingredients

- · Substances
- · CAS No. Description
- CAS: 6119-47-7 Chininhydrochlorid Dihydrat
- Identification number(s)
- EC number: 612-097-2

## 4 First aid measures

- · Description of first aid measures
- · After inhalation: Take affected persons into fresh air and keep quiet.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.

### · After swallowing:

- Rinse out mouth and then drink plenty of water.
- Call for a doctor immediately.

### · Most important symptoms and effects, both acute and delayed

- Cardiovascular disorders Nausea Vomiting Diarrhea Headache Tinnitus Visual disturbances Hematological disorders
- Indication of any immediate medical attention and special treatment needed No further relevant information available.

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# 5 Firefighting measures

- Extinguishing media • Suitable extinguishing agents: Water spray Fire-extinguishing powder Carbon dioxide
- Foam

Use fire extinguishing methods suitable to surrounding conditions.

- For safety reasons unsuitable extinguishing agents: Firmly waterspray
- · Special hazards arising from the substance or mixture
- In case of fire, the following can be released: Carbon monoxide (CO) Carbon dioxide (CO2) Nitrogen oxides (NOx)
- 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
 Do not breathe Dust.
 Ensure adequate ventilation
 Avoid contact with the substance.
 Environmental precautions:
 Do not allow product to reach sewage system or any water course.
 Inform respective authorities in case of seepage into water course or sewage system.
 Methods and material for containment and cleaning up:
 Pick up mechanically.
 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
- Prevent formation of dust.

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). Store only in the original receptacle.

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# Trade name: Chininhydrochlorid Dihydrate, API

(Contd. of page 3) · Information about storage in one common storage facility: Not required. • Further information about storage conditions: Protect from exposure to the light. · 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: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. · Respiratory protection: Dust protection mask. Hand protection Protective gloves Material of gloves Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Butyl rubber, BR Nitrile rubber, NBR Natural rubber, NR The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. Eye/face protection Safety glasses · Body protection: Protective work clothing 9 Physical and chemical properties · Information on basic physical and chemical properties · General Information · Physical state Solid · Colour: White · Odour: Odourless · Odour threshold: Not determined. • Melting point/freezing point: 123 °C · Boiling point or initial boiling point and boiling Undetermined. range Product is not flammable. Flammability

- · Lower and upper explosion limit
- · Lower:

Not determined.

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· Upper:	(Contd. of page 4) Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
·pH	6–6.8
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water at 20 °C:	62.5 g/l
· 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.
Bulk density:	310 kg/m <sup>3</sup>
· Vapour density	Not applicable.
· Particle characteristics	Not determined
• Other information	
· Appearance:	
Form:	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.
· Change in condition	
· Evaporation rate	Not applicable.
Information with regard to physical hazard	
classes	
· Explosives	Void
	Void
<sup>·</sup> Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
<sup>.</sup> Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
<ul> <li>Self-reactive substances and mixtures</li> </ul>	Void
	Void
· Pyrophoric liquids	Void
	Void
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· Pyrophoric solids	Void	( 10,
	Void	
<ul> <li>Self-heating substances and mixtures</li> </ul>	Void	
	Void	
· Substances and mixtures, which emit flam	mable	
gases in contact with water	Void	
-	Void	
· Oxidising liquids	Void	
	Void	
· Oxidising solids	Void	
-	Void	
· Organic peroxides	Void	
	Void	
· Corrosive to metals	Void	
	Void	
· Desensitised explosives	Void	
p	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 No dangerous reactions known.
- **Conditions to avoid** Ditect solar radiation.
- High temperature.
- **Incompatible materials:** Oxidizing agent
- Hazardous decomposition products: Carbon dioxide

Carbon monoxide Nitrogen oxides (NOx)

# **11 Toxicological information**

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if swallowed.
- · LD/LC50 values relevant for classification:
- Oral LD50 1,160 mg/kg (mouse)

### 620 mg/kg (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation

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

- **Respiratory or skin sensitisation** May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.



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· 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 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:

LC50 >100 mg/L /48h (fish: oncorhynchus mykiss)

- EC50 28.4 mg/L /24h (Daphnia pulex)
- Persistence and degradability Easily biodegradable
- · Bioaccumulative potential Non significant accumulation in organisms
- · 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.

The product does not contain substances with endocrine disrupting properties.

- · 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.

# <sup>\*</sup>14 Transport information

· UN number or ID number

Not subject to transport regulations.

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### Trade name: Chininhydrochlorid Dihydrate, API

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· ADR, IMDG, IATA	not regulated	· · · · · · ·
<ul> <li>UN proper shipping name</li> <li>ADR, IMDG, IATA</li> </ul>	not regulated	
Transport hazard class(es)	3	
· ADR, ADN, IMDG, IATA		
· Class	not regulated	
· Packing group	-	
· ADR, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
<ul> <li>Special precautions for user</li> </ul>	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.

# 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.
- · Date of previous version: 10.03.2023

· 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

Acute Tox. 4: Acute toxicity – Category 4

Resp. Sens. 1: Respiratory sensitisation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1

#### \* Data compared to the previous version altered.