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Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2025 Version number 2.00 (replaces version 1.00) Revision: 23.09.2025

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

· Product identifier

· Trade name: <u>Fampridine</u> · Article number: 5233

• CAS Number: 504-24-5 • EC number:

207-987-9

· 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

Acute Tox. 2 H300 Fatal if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.

Acute Tox. 3 H331 Toxic if inhaled.

Skin Corr. 1 H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

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

The substance is classified and labelled according to the CLP regulation.

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· Hazard pictograms



· Signal word Danger

· Hazard statements

H300 Fatal if swallowed.

H311+H331 Toxic in contact with skin or if inhaled.

H314 Causes severe skin burns and eye damage. H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P361+P364 Take off immediately all contaminated clothing and wash it before reuse.

P405 Store locked up.

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: 504-24-5 4-pyridylamine

- Identification number(s)
- EC number: 207-987-9

4 First aid measures

- · Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

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· After inhalation:

Bring the person out of the contaminated area to fresh air.

Call a doctor immediately.

Show product-label or this MSDS.

After skin contact:

Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.

Seek medical advice, even if no immediate symptoms are observed.

· After eye contact:

Rinse opened eye for several minutes under running water.

Seek medical advice, even if no immediate symptoms are observed.

- After swallowing: Do not induce vomiting; call for medical help 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.

· Special hazards arising from the substance or mixture

Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.

- · 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.

Inform respective authorities in case of seepage into water course or sewage system.

Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to section 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.

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- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: Tightly closed.
- 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: 6.1 A Combustible, acutely toxic substances
- 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 section 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.

Store protective clothing separately.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

- · Respiratory protection: Dust protection mask.
- · Hand protection Protective gloves
- Material of gloves

Rubber gloves

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 Tightly sealed goggles
- Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information

· Physical state Solid

· Colour: Light brown · Odour: Characteristic

· Odour threshold: Not determined.

· Melting point/freezing point: 159 °C

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· Boiling point or initial boiling point and boiling

range 273 °C

· Flammability Product is not flammable.

· Lower and upper explosion limit

Not determined. · Lower: · Upper: Not determined. · Flash point: Not applicable. **Decomposition temperature:** Not determined. Not applicable. · pH

· Viscosity:

· Kinematic viscosity Not applicable. · Dynamic: Not applicable.

· Solubility

· water at 20 °C: 83 g/l

Not determined. · Partition coefficient n-octanol/water (log value)

· Vapour pressure:

Not applicable.

Density and/or relative density

Density at 20 °C: 1.25 g/cm³ Relative density Not determined. · Vapour density Not applicable. **Particle characteristics** Not determined

· Other information

· Appearance:

· Form: Solid

· Important information on protection of health

and environment, and on safety.

· Ignition temperature: Not determined.

Explosive properties: Product does not present an explosion hazard.

Change in condition

· Gases under pressure

· Flammable solids

· 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

Void Void

· Flammable liquids Void

Void Void

Void

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Self-reactive substances and mixtures	Void	
	Void	
· Pyrophoric liquids	Void	
	Void	
· Pyrophoric solids	Void	
	Void	
· Self-heating substances and mixtures	Void	
	Void	
· Substances and mixtures, which emit flamn	nable	
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	
	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 No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: When heated to decomposition, emits dangerous fumes.

11 Toxicological information

- Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity

Fatal if swallowed.

Toxic in contact with skin or if inhaled.

· LD/LC50 values relevant for classification:

Oral LD50 20 mg/kg (rat)

Dermal LD50 327 mg/kg (rabbit)

- · Primary irritant effect:
- · Skin corrosion/irritation Causes severe skin burns and eye damage.
- Serious eye damage/irritation Causes serious eye damage.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.

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- · 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 >2.43 mg/L /4d (Fish)

EC50 >17 mg/L /72h (algae)

14.5 mg/L /48h (invertebrates)

- Persistence and degradability Heavily biodegradable
- · 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.

The product does not contain substances with endocrine disrupting properties.

- Other adverse effects
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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· Uncleaned packaging:

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

14 Transport information

· UN number or ID number

· ADR, IMDG, IATA UN2671

· UN proper shipping name

• ADR 2671 AMINOPYRIDINES, ENVIRONMENTALLY

HAZARDOUS

· IMDG AMINOPYRIDINES · IATA Aminopyridines

· Transport hazard class(es)

· ADR, IMDG, IATA

· Class 6.1 Toxic substances.

· Label 6.1

· Packing group

· ADR, IMDG, IATA

· Environmental hazards: Environmentally hazardous substance, solid

Marine pollutant:
 Special marking (ADR):
 Special precautions for user
 Symbol (fish and tree)
 Warning: Toxic substances.

· Hazard identification number (Kemler code): 60 · EMS Number: F-A,S-A

· Segregation groups SGG18 - Alkalis

Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· ADR

Limited quantities (LQ)
 Transport category
 Tunnel restriction code
 500 g
 D/E

·IMDG

· Limited quantities (LQ) 500 g

· UN "Model Regulation": UN 2671 AMINOPYRIDINES, 6.1, II,

ENVIRONMENTALLY HAZARDOUS

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.

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· National regulations:

Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 6.1 A Combustible, acutely toxic substances

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.
- · Version number of previous version: 1.00
- 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. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1: Skin corrosion/irritation – Category 1

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2