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

Printing date 09.08.2021 Version number 2.00 Revision: 09.08.2021

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

· Product identifier

· Trade name: Fampridine

· 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.

3 Composition/information on ingredients

· Chemical characterisation: Substances

· CAS No. Description 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.
- · Information for doctor:
- · 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 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.

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7 Handling and storage

- · Handling:
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- 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

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- Ingredients with limit values that require monitoring at the workplace:

CAS: 504-24-5 4-pyridylamine

MAK (Germany) vgl.Abschn. III

- · Exposure controls
- · 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.
- Protection of hands: 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 protection: Tightly sealed goggles
- · Body protection: Protective work clothing

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9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Solid
Colour: Light brown
Odour: Characteristic
Odour threshold: Not determined.

pH-value: Not applicable.

· Change in condition

Melting point/freezing point: $159 \, ^{\circ}\text{C}$ Initial boiling point and boiling range: $273 \, ^{\circ}\text{C}$

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined.Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not applicable.

Density at 20 °C:
Relative density
Not determined.
Vapour density
Not applicable.
Evaporation rate
Not applicable.

· Solubility in / Miscibility with

water at 20 °C: 83 g/l

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable. **Kinematic:** Not applicable.

• Other information No further relevant information available.

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.

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- · 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 toxicological effects
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- 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 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.

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
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Ecotoxical 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.

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Toxic for aquatic organisms

- Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

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

· UN-Number

· IMDG

· IATA

· ADR, IMDG, IATA UN2671

UN proper shipping name

· **ADR** 2671 AMINOPYRIDINES, ENVIRONMENTALLY

HAZARDOUS AMINOPYRIDINES 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

Special marking (ADR):Special precautions for userSymbol (fish and tree)Warning: Toxic substances.

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

Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

· Transport/Additional information:

· ADR

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

·IMDG

· Limited quantities (LQ) 500 g

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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
- · 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.
- · 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

* Data compared to the previous version altered.

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