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

Printing date 29.09.2025 Version number 1.00 Revision: 29.09.2025

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

· Product identifier

· Trade name: Hyoscine hydrobromide

· Article number: 6610

· CAS Number:

114-49-8

· EC number:

204-050-6

· Index number:

614-015-00-0

- · **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. 1 H310 Fatal in contact with skin.

Acute Tox. 2 H330 Fatal if inhaled.

- · 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+H310+H330 Fatal if swallowed, in contact with skin or if inhaled.

· Precautionary statements

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

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P320 Specific treatment is urgent (see on this label).

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: 114-49-8 Hyoscine hydrobromide

- Identification number(s)
- **EC number:** 204-050-6
- · Index number: 614-015-00-0

#### 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.

· After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

• After skin contact: Immediately wash with water and soap and rinse thoroughly.

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- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- 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.
- · 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

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Information about fire - and explosion protection:

Dust can combine with air to form an explosive mixture.

- · 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.

Information about storage in one common storage facility: Not required.

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- · Further information about storage conditions: Store receptacle in a well ventilated area.
- 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 and skin.

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

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
White

Odourless
Not determined.

188–193 °C

· Boiling point or initial boiling point and boiling

range Undetermined.

• Flammability Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.Upper: Not determined.Flash point: Not applicable.

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· **Decomposition temperature:** Not determined.

· pH (50 g/l) at 25 °C

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

Solubility

water: Not determined.
 Partition coefficient n-octanol/water (log value)
 Vapour pressure: Not applicable.

· Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Bulk density: 500 kg/m³
 Vapour density Not applicable.
 Particle characteristics Not determined

· Other information

· Appearance:

· Form: Powder

· 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

• Evaporation rate Not applicable.

Information with regard to physical hazard classes

· Explosives Void · Flammable gases Void Void · Aerosols · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void **Pyrophoric solids** Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable Void gases in contact with water

gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void
Corrosive to metals Void
Desensitised explosives Void

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## 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:

Hydrogen bromide

Nitrogen oxides

### 11 Toxicological information

- Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Fatal if swallowed, in contact with skin or if inhaled.
- LD/LC50 values relevant for classification:

Oral LD50 1,270 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/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 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.
- · 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: 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 (Contd. on page 7)

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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 3 (German Regulation) (Assessment by list): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

#### 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 or ID number

· ADR, IMDG, IATA UN1544

· UN proper shipping name

· ADR 1544 ALKALOIDS, SOLID, N.O.S. (Hyoscine

hydrobromide)

· IMDG ALKALOIDS, SOLID, N.O.S. (Hyoscine hydrobromide)

· IATA Alkaloids, solid, n.o.s. (Hyoscine hydrobromide)

· Transport hazard class(es)

· ADR, IMDG, IATA

· Class 6.1 Toxic substances.

· Label 6.1

· Packing group

· ADR, IMDG, IATA

Environmental hazards: Not applicable.

• Special precautions for user Warning: Toxic substances.

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

· 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

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· IMDG

· Limited quantities (LQ)

UN "Model Regulation": UN 1544 ALKALOIDS, SOLID, N.O.S. (HYOSCINE

HYDROBROMIDE), 6.1, II

### 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: 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. 1: Acute toxicity – Category 1

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