

Trade name: Ephedrini hydrochloridum

Substance number: 063408

Version: 8 / CH

Date revised: 20.06.2023

Replaces Version: 7 / CH

Print date: 20.06.23

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

1.1. Product identifier

Ephedrini hydrochloridum

Item No. 06340800

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Active pharmaceutical substance, Manufacture of pharmaceutical products

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification ***

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

Precautionary statements ***

P264.1	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P330	Rinse mouth.
P501.3	Disposal in compliance with local and national regulations.

Trade name: Ephedrini hydrochloridum

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Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains ephedrine hydrochloride

2.3. Other hazards

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients**Hazardous ingredients****ephedrine hydrochloride**

CAS No.	50-98-6		
EINECS no.	200-074-6		
Concentration	>= 50		%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 4	H302	
ATE	oral	710	mg/kg

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

Remove contaminated clothing immediately and dispose of safely. Adhere to personal protective measures when giving first aid. Remove affected person from danger area. If the patient is likely to become unconscious, place and transport in stable sideways position. In any case show the physician the Safety Data Sheet. Poisonous symptoms can first be observed after several hours, therefore medical observation for at least 48 hours is necessary.

After inhalation

Remove the casualty into fresh air and keep him calm. When spray fog inhaled, seek medical aid immediately and show the physician the packing or the packing label.

After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off immediately with soap and water and rinse well.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately.

After ingestion

Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Summon a doctor immediately.

4.3. Indication of any immediate medical attention and special treatment needed**Hints for the physician / treatment**

Symptomatic treatment (decontamination, vital functions), no specific antidote known.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water, Dry chemical extinguisher, Carbon dioxide, Foam, Extinguishing measures to suit surroundings

5.2. Special hazards arising from the substance or mixture

Trade name: Ephedrini hydrochloridum

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8.2. Exposure controls

Exposure controls

See Section 7. No measures exceeding the ones mentioned necessary.

General protective and hygiene measures

Avoid contact with skin and eyes. Keep away from food-stuffs, beverages and feed-stocks. At work do not eat, drink, smoke or take drugs. Take off immediately all contaminated clothing. Store work clothing separately.

Respiratory protection

Breathing apparatus in the event of vapours. Breathing apparatus in the event of aerosol. Particle filter P2

Hand protection

Chemical resistant gloves

Use Permanent hand contact

Appropriate Material nitrile rubber - NBR

Material thickness 0.4 mm

Breakthrough time > 480 min

Chemical resistant gloves

Use Permanent hand contact

Appropriate Material Butyl rubber

Material thickness 0.7 mm

Breakthrough time > 480 min

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Hand protection must comply with EN 374.

Eye protection

Safety glasses with side protection shield; Eye protection must comply with EN 166.

Body protection

Protective clothing

SECTION 9: Physical and chemical properties ***

9.1. Information on basic physical and chemical properties

Physical state solid

Colour colourless

Odour odourless

Physical state Powder

Melting point

Value 217 to 220 °C

Boiling point or initial boiling point and boiling range

Remarks not determined

Flammability

Not ignitable

Flash point

Value °C

Remarks Not applicable

Ignition temperature ***

Remarks Not applicable

pH value

Trade name: Ephedrini hydrochloridum

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Replaces Version: 7 / CH

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Value	4.5	to	6.5
Concentration/H ₂ O	50	g/l	

Vapour pressure

Remarks Not applicable

Density and/or relative densityValue 1.28 g/cm³**9.2. Other information****Solubility in water**

Value	300	g/l
Temperature	20	°C

Auto-ignition temperature

Remarks Not applicable

Other information

The product is not dangerous for explosions. Forms explosive mixture with air are possible.

SECTION 10: Stability and reactivity**10.1. Reactivity**

No decomposition if stored and applied as directed.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No decomposition if stored and applied as directed.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

None known

SECTION 11: Toxicological information *****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

ATE	710	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)**ephedrine hydrochloride**

Species	rat	
LD50	710	mg/kg

Acute dermal toxicity (Components)**ephedrine hydrochloride**

Species	rat	
LD50	> 2000	mg/kg

Acute inhalative toxicity (Components)**ephedrine hydrochloride**

Trade name: Ephedrini hydrochloridum

Substance number: 063408

Version: 8 / CH

Date revised: 20.06.2023

Replaces Version: 7 / CH

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Species	rat		
LC50		5.2	mg/l

Skin corrosion/irritation (Components)

ephedrine hydrochloride	
evaluation	slightly irritant

Serious eye damage/irritation (Components)

ephedrine hydrochloride	
evaluation	slightly irritant

Sensitization (Components)

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

Mutagenicity (Components)

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

Reproduction toxicity (Components)

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

Carcinogenicity (Components)

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

Specific Target Organ Toxicity (STOT) (Components)

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

11.2 Information on other hazards**Endocrine disrupting properties with respect to humans**

This substance does not have endocrine disrupting properties with respect to humans.

Experience in practice

spasms. nausea. Kidney damage is possible.

SECTION 12: Ecological information *****12.1. Toxicity****Fish toxicity (Components)**

ephedrine hydrochloride		
Species	golden orfe (Leuciscus idus)	
LC50	460	
Duration of exposure	96 h	
		mg/l

Daphnia toxicity (Components)

ephedrine hydrochloride		
Species	Daphnia magna	
EC50	56.1	
		mg/l

Algae toxicity (Components)

ephedrine hydrochloride		
Species	Algae	
EC50	90.7	
Duration of exposure	72 h	
		mg/l

Trade name: Ephedrini hydrochloridum

Substance number: 063408

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Replaces Version: 7 / CH

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Bacteria toxicity (Components)**ephedrine hydrochloride**

Species	Pseudomonas putida	
EC50	6400	mg/l
Duration of exposure	17	h

12.2. Persistence and degradability**Biodegradability (Components)****ephedrine hydrochloride**

evaluation Readily biodegradable

12.3. Bioaccumulative potential**General information**

No data available

12.4. Mobility in soil**General information**

No data available

12.5. Results of PBT and vPvB assessment**Results of PBT and vPvB assessment *****

The Substance does not meet PBT-criteria.

This substance does not meet the vPvB-criteria.

12.6 Endocrine disrupting properties**Endocrine disrupting properties with respect to the environment**

This substance does not have endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects**General information / ecology**

Do not allow it to reach ground water, water bodies or sewage system.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information *****15.1. Safety, health and environmental regulations/legislation specific for the substance**

Trade name: Ephedrini hydrochloridum

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or mixture**Water Hazard Class (Germany) *****

Water Hazard Class (Germany) WGK 1

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.