

Trade name: Ephedrini hydrochloridum

Substance number: 063408

Version: 7 / CH

Date revised: 17.12.2018

Replaces Version: 6 / CH

Print date: 01.10.19

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

1.1. Product identifier

Ephedrini hydrochloridum

Item No. 06340800

Registration no.

CAS No. 50-98-6

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

Use of the substance/preparation

Active pharmaceutical substance

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.

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P330

Rinse mouth.

P501.9

Dispose of contents/container as problematic waste.

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

contains

ephedrine hydrochloride

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

CAS No. 50-98-6

EINECS no. 200-074-6

Concentration \geq 50 %

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

Acute Tox. 4

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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.

After inhalation

Remove the casualty into fresh air and keep him calm. Summon a doctor immediately.

After skin contact

Wash off immediately with soap and water and rinse well.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Eye doctor.

After ingestion

Rinse out mouth and give plenty of water to drink. Take medical treatment.

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. On pulmonary edema give corticosteroides (e.g. Prednisolon).

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

Water, Dry chemical extinguisher, Carbon dioxide, Foam

5.2. Special hazards arising from the substance or mixture

In the event of fire the following can be released: Hydrogen chloride (HCl)

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

Use self-contained breathing apparatus.

Other information

Cool endangered containers with water spray jet. Collect contaminated fire-fighting water separately,

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must not be discharged into the drains. Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use breathing apparatus if exposed to vapours/dust/aerosol. Avoid dust formation.

6.2. Environmental precautions

Do not empty into drains. Do not discharge into the subsoil/soil.

6.3. Methods and material for containment and cleaning up

For small amounts: take up with appropriate instrument and dispose. For large amounts: take up with appropriate instrument and dispose.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid dust formation. Use breathing apparatus when transferring large quantities without exhaust ventilation facilities. Procure extinguisher

Advice on protection against fire and explosion

Take action to prevent static discharges. Keep away from sources of ignition.

Classification of fires / temperature class / Ignition group / Dust explosion class

Dust explosion class Capable of dust explosion

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value	15	30	°C
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Requirements for storage rooms and vessels

Keep container tightly closed and dry.

Further information on storage conditions

Protect from light.

SECTION 8: Exposure controls/personal protection

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

Appropriate Material

Material thickness

Permanent hand contact

nitrile rubber - NBR

0.4 mm

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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.

Eye protection

Safety glasses with side protection shield

Body protection

Protective clothing

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties****Form** Crystalline powder**Colour** white**Odour** almost odourless**pH value**

Value appr. 4.5 to 6.5

Concentration/H₂O 50 g/l

Source Safety Data Sheet Supplier

Melting point

Value appr. 217 to 220 °C

Source Safety Data Sheet Supplier

Flash point

Value °C

Remarks Not applicable

Flammability (solid, gas)

Not ignitable

DensityValue 1.28 g/cm³**Solubility in water**

Value 300 g/l

Temperature 20 °C

Source Safety Data Sheet Supplier

Partition coefficient: n-octanol/water

log Pow -1.54

Temperature 23 °C

Source Safety Data Sheet Supplier

Ignition temperature

Value appr. 330 °C

Method DIN 51794

Source Safety Data Sheet Supplier

Auto-ignition temperature

Remarks Not applicable

Decomposition temperature

Value 212 °C

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Remarks

No decomposition if used as prescribed.

9.2. Other information**Bulk density**

Value

appr. 600

kg/m³

Source

Safety Data Sheet Supplier

Other information

Forms explosive mixture with air are possible.

SECTION 10: Stability and reactivity**10.4. Conditions to avoid**

Keep away from sources of heat and ignition.

10.6. Hazardous decomposition products

Flammable gases/vapours

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

Species

rat

LD50

710

mg/kg

Method

BASF-test

Acute dermal toxicity

Species

rat

LD50

> 2.000

mg/kg

Remarks

no toxicity

Source

Safety Data Sheet Supplier

Acute inhalational toxicity

Species

rat

LD50

> 5.2

mg/l

Remarks

low toxicity

Source

Safety Data Sheet Supplier

Skin corrosion/irritation

Species

rabbit

Method

Draize method

Remarks

None

Source

Safety Data Sheet Supplier

Serious eye damage/irritation

Remarks

None

Source

Safety Data Sheet Supplier

Sensitization

Remarks

No data available.

Mutagenicity

Remarks

None

Source

Safety Data Sheet Supplier

Reproductive toxicity

Remarks

No data available.

Carcinogenicity

evaluation

No indications of carcinogenic effects are available from long-term trials.

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Remarks

Test conducted with a similar formulation.

Experience in practice

Inhalation may lead to irritation of the respiratory tract.

SECTION 12: Ecological information**12.1. Toxicity****Fish toxicity**

Species	golden orfe (<i>Leuciscus idus</i>)	
LC50	appr. 460	mg/l
Duration of exposure	96	h
Method	DIN 38412 T.15	
Remarks	The details of the toxic effect relate to the nominal concentration.	
Source	Safety Data Sheet Supplier	

Daphnia toxicity

Species	Daphnia magna	
EC50	10	to 100 mg/l
Duration of exposure	48	h
Method	OECD 202	
Remarks	The details of the toxic effect relate to the nominal concentration.	
Source	Safety Data Sheet Supplier	

Algae toxicity

Species	Desmodesmus subspicatus	
EC50	90.7	mg/l
Duration of exposure	72	h
Remarks	The details of the toxic effect relate to the nominal concentration.	
Source	Safety Data Sheet Supplier	

Bacteria toxicity

Species	activated sludge	
EC20	appr. 700	mg/l
Duration of exposure	0.5	h
Method	OECD 209	
Source	Safety Data Sheet Supplier	
Species	<i>Pseudomonas putida</i>	
EC50	6.400	mg/l
Duration of exposure	17	h
Method	DIN 38412 Part 8	
Remarks	The details of the toxic effect relate to the nominal concentration.	
Source	Safety Data Sheet Supplier	

12.2. Persistence and degradability**Physico-chemical eliminability**

Value	90	to	100	%
Duration of test	18	d		
evaluation	Readily biodegradable (according to OECD criteria)			
Source	Safety Data Sheet Supplier			

Biodegradability

Remarks	The product is readily biodegradable according to OECD criteria.
Source	Safety Data Sheet Supplier

12.3. Bioaccumulative potential**Partition coefficient: n-octanol/water**

log Pow	-1.54
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Temperature
Source23 °C
Safety Data Sheet Supplier**12.6. Other adverse effects****Behaviour in environment compartments**

Because of the n-octanol/water distribution coefficient (log pOW) accumulation in organisms is not possible.

General information / ecology

Harmful to aquatic organisms.

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	Non-dangerous goods	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 or mixture****Water Hazard Class (Germany)**

Water Hazard Class (Germany) WGK 3

Remarks Classification according to Annex 4 VwVwS

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.