Safety data sheet in accordance with regulation (EC) No 1907/2006



Substance number: 063408

Version: 8 / CH Replaces Version: 7 / CH Date revised: 20.06.2023 Print date: 20.06.23

HANSELER

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 pharmacutical substance, Manufacture of pharmacutical 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

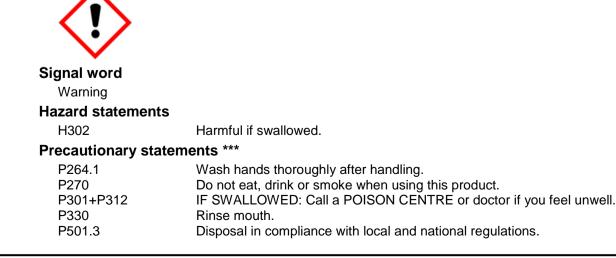
Classification (Regulation (EC) No. 1272/2008)

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





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

ephedrine hydrochloride

2.3. Other hazards

contains

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 (Re	gulation (EC) No. 7	1272/2008)		
	Acute Tox. 4		H302	
ATE d	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, there- fore 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



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In the event of fire the following can be released: Hydrogen chloride (HCl); Nitrogen oxides (NOx); Hydrogen chloride gas

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Wear protective clothing.

Other information

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

To pick up dry. Clean up affected area. When picked up, treat material as prescribed under Section 13 "Disposal".

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8. Information regarding waste disposal, see Section 13.

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

Requirements for storage rooms and vessels

Keep container tightly closed and dry.

Storage classes

Storage class according to TRGS 510	11
Storage category (Switzerland)	11/13

Combustible solids Other solid hazardous substances with classification/labelling hazardous

°C

25

Further information on storage conditions

Protect from light.

SECTION 8: Exposure controls/personal protection

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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	Pern	nanent har	nd contact
Appropriate Material	nitrile	e rubber - I	NBR
Material thickness		0.4	mm
Breakthrough time	>	480	min
Chemical resistant gloves			
Use	Pern	nanent har	nd contact
Appropriate Material	Buty	l 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 boil	ing ran	ge	
Remarks	not determined			
Flammability				
Not ignitable				
Flash point				
Value	°C			
Remarks	Not applicable			
Ignition temperature *	**			
Remarks	Not applicable			
pH value				

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Substance number 000400		0 / 01 1			
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	Replaces	s Version	: 7/CH		Print date: 20.06.2
Value	4.5	to	6.5		
Concentration/H2O	50	g/l	0.0		
Vapour pressure		-			
Remarks	Not applicable				
Density and/or relative de					
Value	1.28			g/cm³	
9.2. Other information				-	
Solubility in water					
Value	300			g/l	
Temperature	20	°C		9/1	
Auto-ignition temperature					
Remarks	Not applicable				
Other information					
The product is not dangerou	us for explosions. For	ms esplo	osive mixtu	e with air ar	e possible.
SECTION 10: Stability an	<u>d reactivity</u>				
-	-				
10.1. Reactivity No decomposition if stored	and applied as directo	ad			
	and applied as directed	ea.			
10.2. Chemical stability No decomposition if stored					
10.2. Chemical stability	and applied as directe				
10.2. Chemical stability No decomposition if stored 10.3. Possibility of hazardou	and applied as directe us reactions own.	ed.			
 10.2. Chemical stability No decomposition if stored 10.3. Possibility of hazardou No hazardous reactions known 10.4. Conditions to avoid 	and applied as directe us reactions own. and applied as directe	ed.			
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 10.2. Chemical stability No decomposition if stored 10.3. Possibility of hazardou No hazardous reactions known 10.4. Conditions to avoid No decomposition if stored 10.5. Incompatible materials None known 10.6. Hazardous decomposit None known SECTION 11: Toxicologic 11.1 Information on hazard of Acute oral toxicity ATE Method Acute oral toxicity (Composite Species LD50 Acute dermal toxicity (Composite Acute oral toxicity (Composite Acute dermal toxicity (Composite Acute dermal	and applied as directer us reactions own. and applied as directer tion products cal information classes as define calculated value (R onents) rat 710	ed. ed. <u>1 ***</u> ed in R (-	mg/kg 1272/2008)	1272/2008
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Trade name: Ephedrini hydrochlorid	um			
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Species	rat			
LC50		5.2	mg/l	
Skin corrosion/irritation (C	compon	ents)		
ephedrine hydrochloride evaluation	slightly	rirritant		
Serious eye damage/irritat	ion (Co	mponents)		
ephedrine hydrochloride evaluation	slightly	rirritant		
Sensitization (Component	s)			
ephedrine hydrochloride Remarks	Based	on available data, the	classification crite	eria are not met
Mutagenicity (Component				
ephedrine hydrochloride evaluation	-	on available data, the	classification crite	aria ara not met
Reproduction toxicity (Co				ena are not met.
ephedrine hydrochloride evaluation	-	on available data, the	classification crite	oria are not mot
Carcinogenicity (Compone			classification crite	ena ale not met.
	into)			
ephedrine hydrochloride evaluation	Based	on available data, the	classification crite	eria are not met.
Specific Target Organ Tox				
ephedrine hydrochloride Remarks		on available data, the		eria are not met.
11.2 Information on other ha		,		
Endocrine disrupting prop		vith respect to hun	nans	
This substance does not ha	ve endoc	rine disrupting proper	ties with respect to	o humans.
Experience in practice				
spasms. nausea. Kidney da	mange is	s possible.		
SECTION 12: Ecological	inform	nation ***		
12.1. Toxicity				
Fish toxicity (Components	5)			
ephedrine hydrochloride				
Species	golden	orfe (Leuciscus idus)		
LC50 Duration of exposure		460 96 h	mg/l	
Daphnia toxicity (Compon	onte)	90 11		
	enisj			
ephedrine hydrochloride Species EC50	Daphn	ia magna 56.1	mg/l	
Algae toxicity (Componen	ts)	-		
ephedrine hydrochloride Species	Algae			
EC50		90.7	mg/l	

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Bacteria toxicity (Cor	nponents)		
ephedrine hydrochlori	ide		
Species	Pseudomonas putio		
EC50 Duration of exposure	6400 17	mg/l h	
12.2. Persistence and d	egradability		
Biodegradability (Cor	•		
ephedrine hydrochlori evaluation	i de Readily biodegrada	ble	
12.3. Bioaccumulative p			
General information			
No data available			
12.4. Mobility in soil			
General information			
No data available			
12.5. Results of PBT an	d vPvB assessment		
Results of PBT and v			
The Substance does	not meet PBT-criteria. not meet the vPvB-criteria.		
12.6 Endocrine disrupti	ng properties		
	properties with respec not have endocrine disruptir	t to the envrionment ng properties with respect to r	non-target organisms.
12.7. Other adverse effe	ects		
General information /	′ ecology h ground water, water bodie	es or sewage system	
SECTION 13: Dispos	-		
13.1. Waste treatment n			
-	lations for the product be with local and national reg	nulations	
Disposal recommend	•	Julations.	
Dispose of as unused			
SECTION 14: Transp	ort 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: Regulat	tory information ***	*	

15.1. Safety, health and environmental regulations/legislation specific for the substance

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or mixture

H302

Water Hazard Class (Germany) ***

Water Hazard Class WGK 1 (Germany) Remarks Derivat

Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information

Hazard statements listed in Chapter 3

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.