

Trade name: Codeini hydrochloridum dihydricum

Substance number: 051450

Version: 3 / CH

Date revised: 02.09.2020

Replaces Version: 2 / CH

Print date: 02.09.20

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

1.1. Product identifier

Codeini hydrochloridum dihydricum

Item No. 05145000

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

Use of the substance/preparation

Active pharmaceutical substance, Chemical for synthesis

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. 3	H301
Acute Tox. 3	H311
Acute Tox. 3	H331
Resp. Sens. 1	H334
Skin Sens. 1	H317
Repr. 2	H361fd

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

Danger

Hazard statements ***

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317

May cause an allergic skin reaction.

Trade name: Codeini hydrochloridum dihydricum

Substance number: 051450

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H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
 H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

Precautionary statements ***

P201 Obtain special instructions before use.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P284 [In case of inadequate ventilation] wear respiratory protection.
 P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor.
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P308+P313 IF exposed or concerned: Get medicinal advice/attention.
 P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

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

contains *** codeine hydrochloride

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

CAS No.	1422-07-7		
EINECS no.	215-829-5		
Concentration	>=	100	%
Classification (Regulation (EC) No. 1272/2008)			
	Acute Tox. 3		H301
	Acute Tox. 3		H311
	Acute Tox. 3		H331
	Skin Sens. 1		H317
	Resp. Sens. 1		H334
	Repr. 2		H361

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

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

After skin contact

Remove contaminated clothing. 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 mouth thoroughly with water. Summon a doctor immediately.

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

Water spray jet, Foam, Dry chemical extinguisher, Carbon dioxide

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Trade name: Codeini hydrochloridum dihydricum

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Version: 3 / CH

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In case of combustion, evolution of health hazardous partially burned gases. Nitrogen oxides (NO_x); Hydrogen chloride (HCl)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Use personal protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Do not discharge into surface waters/groundwater. Do not empty into drains, caverns and basements.

6.3. Methods and material for containment and cleaning up

Avoid raising dust. Take up mechanically and collect in suitable container for disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid inhaling dusts/billows/ steams.

Advice on protection against fire and explosion

Take action to prevent static discharges. Substance/product in the dry state promotes fires.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value < 30 °C

Requirements for storage rooms and vessels

Keep only in original packaging.

Hints on storage assembly

Do not store together with: Metals

Storage classes

Storage class according to TRGS 510	6.1B	Non-combustible substances of acute toxicity, categories 1 and 2 / very toxic hazardous substances
Storage category (Switzerland)	6.1	Toxic substances

Further information on storage conditions

Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Respiratory protection

Dust mask

Hand protection

Gloves
Appropriate Material rubber

Eye protection

Trade name: Codeini hydrochloridum dihydricum

Substance number: 051450

Version: 3 / CH

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Safety glasses

Body protection

Protective clothing

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Form	Crystalline powder		
Colour	white		
pH value			
Value	8	to	9
Concentration/H ₂ O	4	%	
Temperature	20	°C	
Melting point			
Value	280		°C
Flash point			
Value			°C
Remarks	Not applicable		
Solubility in water			
Value	50		g/l
Temperature	20	°C	
Remarks	soluble		
Solubility(ies)			
Ethanol			
Value	2		g/l
Remarks	easily soluble		
Explosive properties			
evaluation	Not applicable		
Oxidising properties			
Remarks	Not applicable		

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 reactionsIn a fire, hazardous decomposition products may be produced. Nitrogen oxides (NO_x)**10.4. Conditions to avoid**

Protect from light. Protect from atmospheric moisture and water.

10.5. Incompatible materials

Oxidising agents, Alkalies

10.6. Hazardous decomposition productsIn the event of fire the following can be released: nitrous oxides (NO_x), Hydrogen chloride (HCl)**SECTION 11: Toxicological information**

Trade name: Codeini hydrochloridum dihydricum

Substance number: 051450

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11.1. Information on toxicological effects

Acute oral toxicity

ATE	266	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)

codeine hydrochloride

Species	mouse			
LD50	266	to	615	mg/kg

Acute dermal toxicity

ATE	300	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute inhalational toxicity

ATE	3	mg/l
Administration/Form	Vapors	
Method	calculated value (Regulation (EC) No. 1272/2008)	
ATE	0.5	mg/l
Administration/Form	Dust/Mist	
Method	calculated value (Regulation (EC) No. 1272/2008)	

Skin corrosion/irritation

evaluation	irritant effect possible
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Serious eye damage/irritation

evaluation	irritant effect possible
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Experience in practice

Symptoms and signs include headache, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness. vomiting. May cause allergic reactions by inhalation. Alcohol intake increases the toxic effect.

SECTION 12: Ecological information

12.1. Toxicity

Fish toxicity

Remarks	No data available.
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Fish toxicity (Components)

codeine hydrochloride

EC50	1	to	10	mg/l
Duration of exposure	96	h		
Method	QSAR			

Daphnia toxicity (Components)

codeine hydrochloride

Species	Daphnia pulex			
EC50	63			mg/l
Duration of exposure	24	h		

Algae toxicity (Components)

codeine hydrochloride

EC50	10	to	100	mg/l
Duration of exposure	96	h		
Source	calculated value			
Source	QSAR			

Trade name: Codeini hydrochloridum dihydricum

Substance number: 051450

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12.2. Persistence and degradability**Biodegradability**

Remarks No data available.

12.3. Bioaccumulative potential**General information**

Not applicable

12.4. Mobility in soil**Mobility in soil**

Mobile in soils

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

No data available

12.6. Other adverse effects**General information**

No data available




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
Tunnel restriction code	D/E		
14.1. UN number	1544	1544	1544
14.2. UN proper shipping name	ALKALOIDS, SOLID, N.O.S.	ALKALOIDS, SOLID, N.O.S.	ALKALOIDS, SOLID, N.O.S.
14.3. Transport hazard class(es)	6.1	6.1	6.1
Label			
14.4. Packing group	II	II	II
Limited Quantity	500 g		
Transport category	2		

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Substance number: 051450

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Replaces Version: 2 / CH

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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 WGK 3

(Germany)

Remarks

Derivation of WGK according to Annex 1 No. 5.2 AwSV

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

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

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.

CLP categories listed in Chapter 3

Acute Tox. 3	Acute toxicity, Category 3
Repr. 2	Reproductive toxicity, Category 2
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1

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.