

Trade name: Opium crudum

Substance number: 055810

Version: 3 / CH

Date revised: 24.04.2023

Replaces Version: 2 / CH

Print date: 24.04.23

**SECTION 1: Identification of the substance/mixture and of the company/undertaking \*\*\*****1.1. Product identifier**

Opium crudum

Item No. 05581000

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/preparation**

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

Eye Dam. 1 H318

Skin Sens. 1 H317

Lact. H362

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 \*\*\***

H302

Harmful if swallowed.

H318

Causes serious eye damage.

H317

May cause an allergic skin reaction.

H362

May cause harm to breast-fed children.

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**Precautionary statements \*\*\***

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy and while nursing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor.

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

contains \*\*\* Codeine; Morphine; Thebaine

**2.3. Other hazards**

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

**SECTION 3: Composition/information on ingredients \*\*\*****3.2. Mixtures****Chemical characterization**

Extract of herbal drugs

**Hazardous ingredients \*\*\*****Morphine**

CAS No.	57-27-2				
EINECS no.	200-320-2				
Concentration	>=	10	<	20	%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 4		H302		
	STOT SE 3		H336		Respiratory tract; Route of exposure: inhalative
cATpE	oral		500		mg/kg

**Codeine**

CAS No.	76-57-3				
EINECS no.	200-969-1				
Concentration	>=	3	<	10	%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 4		H302		
	Skin Sens. 1		H317		
	Eye Dam. 1		H318		
	Lact.		H362		
ATE	oral		250		mg/kg

**Thebaine**

CAS No.	115-37-7				
EINECS no.	204-084-1				
Concentration	>=	1	<	5	%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 3		H301		
cATpE	oral		100		mg/kg

**Other information**

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Natural product with variable composition.

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

#### **General information**

If you feel unwell, seek medical advice (show the label where possible).

#### **After inhalation**

Ensure supply of fresh air. When dust is intensively inhaled, seek medical help immediately. Irregular breathing/no breathing: artificial respiration.

#### **After skin contact**

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

#### **After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). By continuous complaints consult a physician.

#### **After ingestion**

Summon a doctor immediately. If swallowed, rinse mouth with water (only if the person is conscious). Induce vomiting if patient is conscious, seek medical advice.

### **4.2. Most important symptoms and effects, both acute and delayed**

When inhaled or swallowed depending on the time and amount, it can give rise to the following symptoms: Irritating to respiratory system. Narcosis, Shortness of breath, if swallowed: Narcosis, Death, Contraction of pupils, Weak pulse, Nausea

### **4.3. Indication of any immediate medical attention and special treatment needed**

#### **Hints for the physician / treatment**

At potential poisoning medical treatment is absolute necessary. Symptomatic treatment and giving of Antidot. Naloxon (Narcanti) i.v. + s.c.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

Water, Alcohol-resistant foam, Carbon dioxide, Dry powder

### **5.2. Special hazards arising from the substance or mixture**

The product is combustible. In the event of fire the following can be released: Carbon dioxide (CO<sub>2</sub>); Nitrogen oxides (NO<sub>x</sub>); Forms explosive mixture with air are possible.

### **5.3. Advice for firefighters**

#### **Special protective equipment for fire-fighting**

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

#### **Other information**

Cool endangered containers with water spray jet. Suppress vapours with water spray jet. 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**

Avoid contact with skin, eyes and clothing. Wear protective equipment. Avoid dust formation. Avoid breathing dust. Ensure supply of fresh air. Keep away from sources of ignition - No smoking. Keep people away and stay on the upwind side.

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**6.2. Environmental precautions**

Do not discharge into the drains/surface waters/groundwater.

**6.3. Methods and material for containment and cleaning up**

To pick up dry. Send in suitable containers for recovery or disposal. Rinse away rest with plenty of water. Avoid raising dust.

**6.4. Reference to other sections**

Refer to protective measures listed in Sections 7 and 8.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Avoid contact with skin, eyes and clothing. Transfer and handle only in enclosed systems. Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid the formation and deposition of dust. Dust deposits that cannot be avoided must be taken up regularly. For personal protection see Section 8.

**7.2. Conditions for safe storage, including any incompatibilities****Recommended storage temperature**

Value 15 25 °C

**Requirements for storage rooms and vessels**

Keep tightly closed in a dry and cool place. Keep only in original packaging. Storage rooms must be properly ventilated.

**Storage classes**

Storage class according to TRGS 510	13	Non- combustible solids
Storage category (Switzerland)	8	Caustic and corrosive substances

**Further information on storage conditions**

Keep locked up and out of the reach of children. Protect from light.

**7.3. Specific end use(s)**

Manufacture of pharmaceutical products

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure limit values****Morphine**

Type	MAK	
Value	0.1	mg/m <sup>3</sup>
Maximum limit value: not available		

**8.2. Exposure controls****Exposure controls**

Avoid inhalation of dusts. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction.

**Respiratory protection**

Breathing apparatus in the event of aerosol.

**Hand protection**

necessary	
Appropriate Material	nitrile rubber - NBR

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Material thickness		0.11	mm
Breakthrough time	>	480	min

**Eye protection**

Safety glasses with side protection shield

**Body protection**

Clothing as usual in the chemical industry.

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

<b>Physical state</b>	Solid mass
<b>Colour</b>	black-brown
<b>Physical state</b>	Lumps
<b>Flash point</b>	
Value	°C
Remarks	Not applicable
<b>Vapour pressure</b>	
Remarks	Not applicable
<b>Density and/or relative density</b>	
Remarks	Not applicable

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

Reactions with strong alkalies and oxidising agents.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

Stable under recommended storage and handling conditions (see section 7).

**10.4. Conditions to avoid**

Protect from exposure to air/oxygen. Protect from light and atmospheric moisture.

**10.5. Incompatible materials**

None known

**10.6. Hazardous decomposition products**

Hazardous determin decomposition products: nitrous oxides (NOx), Carbon monoxide and carbon dioxide

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

ATE	1'360.91	mg/kg
	45	
Method	calculated value (Regulation (EC) No. 1272/2008)	

**Acute oral toxicity (Components)****Codeine**

Species	mouse	
LD50	250	mg/kg

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Remarks anhydrous  
Source RTECS

**Codeine**

Species rat  
LD50 427 mg/kg  
Remarks anhydrous  
Source RTECS

**Skin corrosion/irritation (Components)****Codeine**

evaluation non-irritant

**Serious eye damage/irritation (Components)****Codeine**

evaluation irritant - risk of serious damage to eyes

**Sensitization (Components)****Codeine**

evaluation sensitizing

**Reproduction toxicity (Components)****Codeine**

evaluation May cause harm to breast-fed children.

**Carcinogenicity (Components)****Codeine**

evaluation No indications of carcinogenic effects are available from long-term trials.  
Remarks negative on animals

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

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

**Experience in practice**

After Swallowing: nausea. vomiting. cyanosis. LD (Adult ) = 2 - 3 g

**SECTION 12: Ecological information****12.1. Toxicity****General information**

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

**Daphnia toxicity (Components)****Codeine**

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

**12.2. Persistence and degradability****Biodegradability**

Remarks The product is biodegradable.

**Biodegradability (Components)****Codeine**

evaluation degradable

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

Immobile

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

The product contains no PBT substances

The product contains no vPvB substances.

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

The product does not contain a substance that has endocrine disrupting properties with respect to non-target 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 \*\*\***

	<b>Land transport ADR/RID ***</b>	<b>Marine transport IMDG/GGVSee ***</b>	<b>Air transport ICAO/IATA ***</b>
<b>14.1. UN number</b>	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 or mixture****Water Hazard Class (Germany) \*\*\***

Water Hazard Class (Germany)      WGK 3

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.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H362	May cause harm to breast-fed children.

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**CLP categories listed in Chapter 3**

Acute Tox. 3	Acute toxicity, Category 3
Acute Tox. 4	Acute toxicity, Category 4
Eye Dam. 1	Serious eye damage, Category 1
Lact.	Reproductive toxicity, Lactation
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity - single exposure, Category 3

**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.