

Trade name: Opii tinctura normata

Substance number: 056001

Version: 5 / CH

Date revised: 11.12.2023

Replaces Version: 4 / CH

Print date: 11.12.23

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

1.1. Product identifier

Opii tinctura normata

Item No. 05600300

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

Use of the substance/preparation

Medicinal product

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)

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Flam. Liq. 3 H226

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 ***

H226 Flammable liquid and vapour.

Precautionary statements ***

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P243 Take action to prevent static discharges.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

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P403+P233 with water [or shower].
 P501.3 Store in a well-ventilated place. Keep container tightly closed.
 EUH208 Contains Disposal in compliance with local and national regulations.
 *** Codeine, May produce an allergic reaction.

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

Alcoholic solution
 Extract of herbal drugs

Hazardous ingredients ***

Morphine

CAS No.	57-27-2				
EINECS no.	200-320-2				
Concentration	>= 1	<	5.6	%	
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	

Thebaine

CAS No.	115-37-7				
EINECS no.	204-084-1				
Concentration	>= 0.1	<	1	%	
Classification (Regulation (EC) No. 1272/2008)					
	Acute Tox. 3		H301		
cATpE	oral		100	mg/kg	

Codeine

CAS No.	76-57-3				
EINECS no.	200-969-1				
Concentration	>= 0.1	<	1	%	
Classification (Regulation (EC) No. 1272/2008)					
	Acute Tox. 4		H302		
	Skin Sens. 1		H317		
	Eye Dam. 1		H318		
	Lact.		H362		

Further ingredients

ethanol

CAS No.	64-17-5				
EINECS no.	200-578-6				
Concentration	>= 25	<	50	%	
Advice: [4]					
Classification (Regulation (EC) No. 1272/2008)					

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Flam. Liq. 2

H225

Note

[4] Voluntary information

Other information

The product is an article within the meaning of Article 3 No. 3 of the REACH Regulation and thus not to be labelled according to the CLP regulation. The compilation of the Safety Data sheet is not required according to Article 31 REACH Regulation for articles and is done on a voluntary basis.

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). Take off contaminated clothing and shoes immediately.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment. Irregular breathing/no breathing: artificial respiration.

After skin contact

Wash immediately with plenty of water for several minutes. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Consult a physician if necessary. Rinse out mouth and give plenty of water to drink.

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

Water spray jet, Carbon dioxide, Alcohol-resistant foam, Dry powder, Extinguishing measures to suit surroundings

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Vapours heavier than air. Can build mixtures of gas and air which are capable of explosion. Keep away sources of ignition. Take precautionary measures against static charges.

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

Wear full protective suit. Use self-contained breathing apparatus.

Other information

Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation. Remove persons to safety. Keep away sources of ignition.

6.2. Environmental precautions

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

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6.3. Methods and material for containment and cleaning up

Take up with absorbent material (eg sand, kieselguhr, universal binder). Send in suitable containers for recovery or disposal. Clean up affected area.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value 15 - 25 °C

Requirements for storage rooms and vessels

Unsuitable material: Polypropylene. Polyethylene

Storage classes

Storage class according to TRGS 510	3	Flammable liquid
Storage category (Switzerland)	3	Flammable liquid

Further information on storage conditions

Keep container tightly closed. Protect from light. Keep away from sources of ignition.

SECTION 8: Exposure controls/personal protection ***

8.1. Control parameters

Exposure limit values ***

Morphine

Type	MAK			
Value	0.1	mg/m ³		

Maximum limit value: not available

ethanol

List	SUVA			
Type	MAK			
Value	960	mg/m ³	500	ppm(V)
Short term exposure limit	1920	mg/m ³	1000	ppm(V)

Pregnancy group: S; Remarks: SSc; Formal; INRS NIOSH

Derived No/Minimal Effect Levels (DNEL/DMEL)

ethanol

Type of value	Derived No Effect Level (DNEL)
Reference group	Worker

8.2. Exposure controls

General protective and hygiene measures

Avoid any contact with the body. Observe the usual precautions for handling chemicals. Keep away from food-stuffs, beverages and feed-stocks.

Respiratory protection

necessary; Do not breathe vapours, dust or aerosol. Provide adequate ventilation.

Hand protection

Appropriate Material Gloves / resistant to chemicals

Eye protection

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Tightly fitting safety glasses

Body protection

Fire-resistant protective clothing

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

Liquid

Colour

red-brown

Boiling point or initial boiling point and boiling range

Value > 78 °C

Source Estimated value

Flash point

Value < 26 °C

Source Estimated value

Vapour pressure

Value < 5.8 kPa

Source Estimated value

Density and/or relative density

Value 0.916 to 0.927 g/ml

Remarks Relative Density according specification

9.2. Other information**Efflux time**

Value 11 s

Method DIN EN ISO 2431 - 4 mm

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

Risk of ignition or formation of inflammable gases or vapours with: Air

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

Keep away from sources of heat and ignition. No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Alkaline metals, Ammonia, peroxides, Oxidising agents

10.6. Hazardous decomposition products

Hazardous determin decomposition products: Carbon monoxide, Carbon dioxide, Flammable gases/vapours

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**ATE > 10'000 mg/kg
Method calculated value (Regulation (EC) No. 1272/2008)

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Acute oral toxicity (Components)**Codeine**

Species	mouse		
LD50	250		mg/kg
Remarks	anhydrous		
Source	RTECS		

Codeine

Species	rat		
LD50	427		mg/kg
Remarks	anhydrous		
Source	RTECS		

ethanol

Species	rat		
LD50	7060		mg/kg
Source	Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.		

ethanol

Species	rat		
LD50	10470		mg/kg

Acute dermal toxicity (Components)**ethanol**

Species	rabbit		
LD50	15800		mg/kg

ethanol

NOAEL	8232		mg/kg
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Acute inhalative toxicity (Components)**ethanol**

Species	rat		
LC50	30000		mg/m ³
Duration of exposure	4	h	
Administration/Form	Vapors		

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

evaluation	non-irritant
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ethanol

evaluation	non-irritant
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Serious eye damage/irritation

Remarks	Eye contact with the product may lead to irritation.
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Serious eye damage/irritation (Components)**Codeine**

evaluation	irritant - risk of serious damage to eyes
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ethanol

evaluation	irritant
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Sensitization (Components)**Codeine**

evaluation	sensitizing
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Mutagenicity (Components)**ethanol**

evaluation	No mutagenicity in the Ames-test.
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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

The solvent vapours cause an irritating effect to the respiratory organs. Causes disorders of the central nervous system and can cause headache, respiratory difficulties or unconsciousness. Causes a numb feeling. Liver damage is possible.

Other information

When handled appropriately, even after long years of experience with this product, no adverse health effects are known.

Product specific toxicological data are not known.

SECTION 12: Ecological information**12.1. Toxicity****Fish toxicity**Reference substance ethanol
LC50 > 10000 mg/l**Daphnia toxicity**Reference substance ethanol
Species Daphnia magna
EC0 > 7800 mg/l**Daphnia toxicity (Components)****Codeine**Species Daphnia pulex
EC50 63 mg/l
Duration of exposure 24 h**Algae toxicity**Reference substance ethanol
Species Scenedesmus quadricauda
EC0 > 5000 mg/l**Bacteria toxicity**Reference substance ethanol
Species Pseudomonas putida
EC0 > 6500 mg/l**12.2. Persistence and degradability****Biodegradability**

Remarks The product is biodegradable.

Biodegradability (Components)**Codeine**

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evaluation degradable

ethanol

evaluation Readily biodegradable

Chemical oxygen demand (COD) (Components)**ethanol**

Value 0.93 to 1.67 mg/g

12.3. Bioaccumulative potential**Bioconcentration factor (BCF) (Components)****ethanol**

BCF 0.66

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.

Results of PBT and vPvB assessment (Ingredients)**ethanol**

The Substance doesn't meets PBT/vPvB-criteria

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.

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

Ecological data refers to the main components. Do not allow it to reach soil, 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

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	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
Tunnel restriction code	D/E		
14.1. UN number	1293	1293	1293
14.2. UN proper shipping name	TINCTURES, MEDICINAL (ethanol)	TINCTURES, MEDICINAL (ethanol)	TINCTURES, MEDICINAL (ethanol)
14.3. Transport hazard class(es)	3	3	3
Label			
14.4. Packing group	III	III	III
Limited Quantity	5 l		
Transport category	3		

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 2

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

SECTION 16: Other information

Hazard statements listed in Chapter 3

H226 Flammable liquid and vapour.
 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.

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
 Flam. Liq. 3 Flammable liquid, Category 3
 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: ***

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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.