

Trade name: Propolis tinctura P56

Substance number: 258290

Version: 3 / CH

Date revised: 07.06.2021

Replaces Version: 2 / CH

Print date: 07.06.21

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

1.1. Product identifier

Propolis tinctura P56

Item No. 25829000

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

Use of the substance/preparation

Medicinal product, Active pharmaceutical substance, 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)

Flam. Liq. 2 H225

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 ***

H225 Highly 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.
 Disposal in compliance with local and national regulations.

2.3. Other hazards

In use, may form flammable/explosive vapour-air mixture. Repeated exposure may cause skin dryness or cracking. Irritating to eyes, respiratory system and skin.

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

Medicinal products
 Alcoholic solution

Further ingredients**ethanol**

CAS No.	64-17-5			
EINECS no.	200-578-6			
Concentration		>=	50	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Liq. 2		H225	

Note

[4] Voluntary information

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

Ensure supply of fresh air. In the event of symptoms take medical treatment.

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.). Summon a doctor immediately.

After ingestion

Do not induce vomiting - aspiration hazard. Summon a doctor immediately.

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

Headache, Dizziness, Unconsciousness, Nausea

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

Carbon dioxide, Dry powder, Water spray jet, Extinguish greater fire with water spray or alcohol-resistant foam.

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fires, hazardous combustion gases are formed; Carbon monoxide (CO); Carbon dioxide (CO₂)

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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.

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

Use personal protective clothing. Remove persons to safety. Ensure adequate ventilation. Keep away sources of ignition.

6.2. Environmental precautions

Dilute with lot of water. Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3. Methods and material for containment and cleaning up

Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder, sawdust).

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).

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take action to prevent static discharges.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep tightly closed in a dry and cool place.

Storage classes

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

Further information on storage conditions

Product is hygroscopic. Store only in the open air or in explosion-proof rooms.

SECTION 8: Exposure controls/personal protection *****8.1. Control parameters****Exposure limit values *******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; OAW, FormalkT HU; INRS, NIOSH				

8.2. Exposure controls**General protective and hygiene measures**

Wash hands before breaks and after work.

Respiratory protection

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Not necessary, but do not inhale vapours.

Hand protection

impermeable gloves

Eye protection

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**

Form	liquid	
Colour	light to dark brown	
Odour	aromatic	
Initial boiling point and boiling range		
Value	>= 78	°C
Source	GESTIS-Stoffdatenbank	
Flash point		
Value	13 to 22	°C
Source	GESTIS-Stoffdatenbank	
Vapour pressure		
Value	<= 5.8	kPa
Source	GESTIS-Stoffdatenbank	
Density		
Value	0.83 to 0.85	g/ml
Remarks	Relative Density according specification	
Decomposition temperature		
Remarks	No decomposition if used as prescribed.	

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

Possible incompatibility with materials listed under section 10.5.

10.4. Conditions to avoid

Keep away from sources of heat and ignition.

10.5. Incompatible materialsReactions with strong oxidising agents. Reactions with strong acids. Reactions with earth alkali metals.
Reactions with alkali metals.**10.6. Hazardous decomposition products**

In the event of fire the following can be released: Carbon monoxide and carbon dioxide, Hazardous decomposition products: Flammable gases/vapours

SECTION 11: Toxicological information

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11.1. Information on toxicological effects

Acute oral toxicity (Components)

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

Acute inhalative toxicity (Components)

ethanol

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

Skin corrosion/irritation (Components)

ethanol

evaluation	non-irritant
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Serious eye damage/irritation (Components)

ethanol

evaluation	irritant
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Mutagenicity (Components)

ethanol

evaluation	No mutagenicity in the Ames-test.
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SECTION 12: Ecological information

12.1. Toxicity

General information

There is no data available on the product apart from the information given in this subsection.

12.2. Persistence and degradability

General information

There is no data available on the product apart from the information given in this subsection.

Biodegradability (Components)

ethanol

evaluation	Readily biodegradable
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Chemical oxygen demand (COD) (Components)

ethanol

Value	0.93	to	1.67	mg/g
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12.3. Bioaccumulative potential

General information

There is no data available on the product apart from the information given in this subsection.

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Bioconcentration factor (BCF) (Components)

ethanol

BCF

0.66

12.4. Mobility in soil**General information**

There is no data available on the product apart from the information given in this subsection.

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

There is no data available on the product apart from the information given in this subsection.

Evaluation of persistence and bioaccumulation potential (Components)

ethanol

The Substance doesn't meets PBT/vPvB-criteria

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

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. The product is easily volatile.

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

Disposal in compliance with local and national regulations.

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	II	II	II
Limited Quantity	1 I		
Transport category	2		

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 1

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

SECTION 16: Other information

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.