

Trade name: Vinum tonicum sine cocae

Substance number: 149251

Version: 1 / CH

Date revised: 25.04.2023

Replaces Version: - / CH

Print date: 25.04.23

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

### **1.1. Product identifier**

Vinum tonicum sine cocae

Item No. 14925100

### **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)

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.  
 Disposal in compliance with local and national regulations.

### 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  
 Medicinal products

#### Further ingredients

##### ethanol

CAS No.	64-17-5				
EINECS no.	200-578-6				
Concentration	>=	10	<	25	%
Advice:	[4]				
Classification (Regulation (EC) No. 1272/2008)	Flam. Liq. 2 H225				

##### Sucrose

CAS No.	57-50-1				
EINECS no.	200-334-9				
Concentration	>=	1	<	10	%
Advice:	[4]				

##### water

CAS No.	7732-18-5				
EINECS no.	231-791-2				
Concentration	>=	1	<	10	%
Advice:	[4]				

##### glycerol dihydrogen phosphate

CAS No.	27082-31-1				
EINECS no.	248-215-0				
Concentration			<	1	%
Advice:	[4]				
Classification (Regulation (EC) No. 1272/2008)	Skin Corr. 1B H314				

##### methyl 4-hydroxybenzoate

CAS No.	99-76-3				
EINECS no.	202-785-7				
Registration no.	01-2119463264-40-0003				
Concentration			<	1	%
Advice:	[4]				
Classification (Regulation (EC) No. 1272/2008)	Aquatic Chronic 2 H411				

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**caffeine**

CAS No. 58-08-2  
 EINECS no. 200-362-1  
 Registration no. 01-2119433305-48-0000  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Acute Tox. 4 H302

**strychnine**

CAS No. 57-24-9  
 EINECS no. 200-319-7  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Acute Tox. 1 H310  
 Acute Tox. 2 H300  
 Aquatic Acute 1 H400  
 Aquatic Chronic 1 H410

**brucine**

CAS No. 357-57-3  
 EINECS no. 206-614-7  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Acute Tox. 2 H300  
 Acute Tox. 2 H330  
 Aquatic Chronic 3 H412

**hydrogen cyanide ...%**

CAS No. 74-90-8  
 EINECS no. 200-821-6  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Acute Tox. 1 H310  
 Acute Tox. 2 H300  
 Acute Tox. 2 H330  
 Aquatic Acute 1 H400  
 Aquatic Chronic 1 H410

Additional remarks:

CLP Regulation (EC) No 1272/2008, Annex VI, Note B

**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**

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**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**

In the event of a fire, toxic and combustible gases can be formed. In the event of fire the following can be released: Carbon monoxide (CO); Carbon dioxide (CO<sub>2</sub>)

**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.

**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****Requirements for storage rooms and vessels**

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

**Storage classes**

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

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

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

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

**Derived No/Minimal Effect Levels (DNEL/DMEL)****ethanol**

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Route of exposure	inhalative			
Mode of action	Local effects			
Concentration	1900			mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	oral			
Mode of action	Systemic effects			
Concentration	434			mg/kg/d

**caffeine**

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	dermal			
Mode of action	Systemic effects			
Concentration	25.17			mg/kg

Type of value	Derived No Effect Level (DNEL)			
Reference group	Worker			
Duration of exposure	Long term			
Route of exposure	inhalative			
Mode of action	Systemic effects			
Concentration	44.37			mg/m <sup>3</sup>

**Predicted No Effect Concentration (PNEC)****caffeine**

Type of value	PNEC			
Species	Fresh water			
Concentration	0.087			mg/l

Type of value	PNEC			
Type	Marine			

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Concentration	0.0087	mg/l
Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	10	mg/l
Type of value	PNEC	
Type	Freshwater sediment	
Concentration	0.4	mg/kg
Type of value	PNEC	
Type	Soil	
Concentration	0.0289	mg/kg

## 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

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, clear

**Colour**                                                dark red

**Odour**                                                aromatic

#### Boiling point or initial boiling point and boiling range

Value                                                 > 78                                                 °C

Source                                                Estimated value

#### Flash point

Value                                                 > 24                                                 °C

Source                                                Estimated value

#### Vapour pressure

Value                                                 < 5.8                                                 kPa

Source                                                Estimated value

#### Density and/or relative density

Value                                                 1.06                                                 to                                                 1.1                                                 g/ml

Remarks                                             Relative Density according specification

### 9.2. Other information

#### Efflux time

Value                                                 11                                                         s

Method                                                DIN EN ISO 2431 - 4 mm

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## **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 (Components)**

##### **methyl 4-hydroxybenzoate**

Species	rat		
LD50		2100	mg/kg
Method	OECD 401		

##### **methyl 4-hydroxybenzoate**

Species	guinea pig		
LD50		3000	mg/kg

##### **methyl 4-hydroxybenzoate**

Species	rabbit		
LC50		6000	mg/kg

##### **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 <sup>3</sup>
Duration of exposure	4	h	
Administration/Form	Vapors		

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

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**methyl 4-hydroxybenzoate**

Species	rabbit		
Duration of exposure	24		h
Observation Period	72		h
evaluation	Moderately irritating		
Method	Draize method		

**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)****methyl 4-hydroxybenzoate**

Species	rabbit		
Observation Period	48		h
evaluation	Moderately irritating		
Method	Draize method		

**ethanol**

evaluation	irritant
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**Sensitization (Components)****methyl 4-hydroxybenzoate**

Species	guinea pig
evaluation	non-sensitizing
Method	OECD 406

**Subacute, subchronic, chronic toxicity (Components)****methyl 4-hydroxybenzoate**

Species	rat		
NOAEL	>=	250	mg/kg
Duration of exposure	28		d

**Mutagenicity (Components)****methyl 4-hydroxybenzoate**

evaluation	No mutagenicity according to various in vitro tests.
Method	OECD 471

**ethanol**

evaluation	No mutagenicity in the Ames-test.
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**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**



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## 12.1. Toxicity

### Fish toxicity (Components)

#### methyl 4-hydroxybenzoate

Species	golden orfe ( <i>Leuciscus idus</i> )	
NOEC	50	mg/l
Duration of exposure	48	h

#### methyl 4-hydroxybenzoate

Species	<i>Oryzias latipes</i>	
LC50	59.5	mg/l
Duration of exposure	96	h
Method	OECD 203	

### Daphnia toxicity (Components)

#### methyl 4-hydroxybenzoate

Species	<i>Daphnia magna</i>	
NOEC	0.2	mg/l
Duration of exposure	21	d
Method	OECD 211	
Source	Manufacturer's data	

#### methyl 4-hydroxybenzoate

Species	<i>Daphnia magna</i>	
EC50	11.2	mg/l
Duration of exposure	48	h

### Algae toxicity (Components)

#### methyl 4-hydroxybenzoate

Species	<i>Desmodesmus subspicatus</i>	
EC50	91	mg/l
Duration of exposure	72	h

#### methyl 4-hydroxybenzoate

NOEC	17	mg/l
Duration of exposure	72	h
Method	OECD 201	

### Bacteria toxicity (Components)

#### methyl 4-hydroxybenzoate

Species	<i>Pseudomonas fluorescens</i>	
EC0	500	mg/l

## 12.2. Persistence and degradability

### Biodegradability (Components)

#### methyl 4-hydroxybenzoate

Value	92.2	%
Duration of test	28	d
evaluation	Readily biodegradable	
Method	OECD 301F	

#### methyl 4-hydroxybenzoate

Value	89	%
Duration of test	28	d
evaluation	Readily biodegradable	
Method	OECD 301 B	

#### ethanol

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

ethanol

Value 0.93 to 1.67 mg/g

**12.3. Bioaccumulative potential****Octanol/water partition coefficient (log Pow) (Components)**

methyl 4-hydroxybenzoate

log Pow 1.98

**Bioconcentration factor (BCF) (Components)**

ethanol

BCF 0.66

**12.4. Mobility in soil****Mobility in soil (Components)**

methyl 4-hydroxybenzoate

Highly mobile in soils

**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**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. For this subsection there is no ecotoxicological data available on the product as such.

**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 1

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.

#### **CLP categories listed in Chapter 3**

Flam. Liq. 3      Flammable liquid, 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.