

Trade name: Vini gallici spir ad us.ex.sine sale

Substance number: 141601

Version: 5 / CH

Date revised: 15.06.2022

Replaces Version: 4 / CH

Print date: 15.06.22

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

1.1. Product identifier

Vini gallici spir ad us.ex.sine sale

Item No. 14160100

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)

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.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

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P403+P233
P501.3

lenses, if present and easy to do. Continue rinsing.
Store in a well-ventilated place. Keep container tightly closed.
Disposal in compliance with local and national regulations.

SECTION 3: Composition/information on ingredients ***

3.2. Mixtures

Chemical characterization

Alcoholic solution
Medicinal products

Hazardous ingredients

ethyl acetate

CAS No.	141-78-6			
EINECS no.	205-500-4			
Registration no.	01-2119475103-46-XXXX			
Concentration		<	0.1	%
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Liq. 2			H225
	Eye Irrit. 2			H319
	STOT SE 3			H336

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

water

CAS No.	7732-18-5					
EINECS no.	231-791-2					
Concentration		>=	25	<	50	%
Advice: [4]						

Bornan-2-one

CAS No.	76-22-2			
EINECS no.	200-945-0			
Registration no.	01-2119966156-31-XXXX			
Concentration		<	1	%
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Flam. Sol. 2			H228
	Acute Tox. 4			H302
	Acute Tox. 4			H332
	STOT SE 2			H371

alpha-Pinene, not specified

CAS No.	80-56-8			
EINECS no.	201-291-9			
Concentration		<	1	%
[4]				
Classification (Regulation (EC) No. 1272/2008)				

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Flam. Liq. 3	H226
Asp. Tox. 1	H304
Skin Irrit. 2	H315
Skin Sens. 1	H317
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Concentration limits (Regulation (EC) No. 1272/2008)

Aquatic Acute 1	M = 1
Aquatic Chronic 1	M = 1

beta-Pinene, not specified

CAS No. 127-91-3

EINECS no. 204-872-5

Concentration < 1 %

[4]

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 3	H226
Asp. Tox. 1	H304
Skin Sens. 1	H317
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Concentration limits (Regulation (EC) No. 1272/2008)

Aquatic Acute 1	M = 1
Aquatic Chronic 1	M = 1

(S)-p-mentha-1,8-diene

CAS No. 5989-27-5

EINECS no. 227-813-5

Concentration < 1 %

[4]

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 3	H226
Asp. Tox. 1	H304
Skin Irrit. 2	H315
Skin Sens. 1	H317
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Concentration limits (Regulation (EC) No. 1272/2008)

Aquatic Acute 1	M = 1
Aquatic Chronic 1	M = 1

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

beta-Caryophyllen

CAS No. 87-44-5

EINECS no. 201-746-1

Concentration < 1 %

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Asp. Tox. 1	H304
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p-Isopropyl toluene

CAS No. 99-87-6

EINECS no. 202-796-7

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Concentration < 1 %

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 3 H226

Asp. Tox. 1 H304

Aquatic Chronic 2 H411

7-Methyl-3-methylenocta-1,6-dien

CAS No. 123-35-3

EINECS no. 204-622-5

Concentration < 1 %

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Flam. Liq. 3 H226

Asp. Tox. 1 H304

Skin Irrit. 2 H315

Eye Irrit. 2 H319

Aquatic Acute 1 H400

Aquatic Chronic 1 H410

Concentration limits (Regulation (EC) No. 1272/2008)

M = 1

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

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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 (CO₂)

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**

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 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**

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

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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**

Form	liquid	
Colour	light brown, clear	
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		
Value	0.910 to 0.920	
Remarks	Relative Density according specification	
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

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11.1. Information on toxicological effects

Acute oral toxicity (Components)

7-Methyl-3-methylenocta-1,6-dien

Species	Rats (male/female)	
LD50	> 11390	mg/kg

7-Methyl-3-methylenocta-1,6-dien

Species	Rats (male/female)	
LOAEL	250	mg/kg

beta-Caryophyllen

Species	rat	
LD	> 48	mg/kg
Source	Intratracheal (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

Bornan-2-one

Species	mouse	
LD50	1310 to 5000	mg/kg

ethyl acetate

Species	rat	
LD50	5620	mg/kg
Source	RTECS	

(S)-p-mentha-1,8-diene

Species	rat	
LD50	4400	mg/kg

(S)-p-mentha-1,8-diene

Species	mouse	
NOAEL	1650	mg/kg

(S)-p-mentha-1,8-diene

Species	mouse	
LOAEL	3300	mg/kg

Acute dermal toxicity (Components)

7-Methyl-3-methylenocta-1,6-dien

Species	rabbit	
LD50	> 5000	mg/kg

beta-Caryophyllen

Remarks	No data available.
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ethanol

Species	rabbit	
LD50	15800	mg/kg

Bornan-2-one

Species	rabbit	
LD50	> 5000	mg/kg

ethyl acetate

Species	rabbit	
	> 18000	mg/kg

(S)-p-mentha-1,8-diene

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Species	rabbit		
LD50	>	5000	mg/kg

Acute inhalative toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks No data available.

beta-Caryophyllen

Remarks No data available.

ethanol

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

Bornan-2-one

LC50		1.5	mg/l
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(S)-p-mentha-1,8-diene

Remarks No data available.

Skin corrosion/irritation (Components)**7-Methyl-3-methylenocta-1,6-dien**

Species	rabbit		
Observation Period		24	h
evaluation	irritant		

beta-Caryophyllen

Species	rabbit		
Duration of exposure		24	h
evaluation	non-irritant		
Method	Draize method		
Source	RTECS		

ethanol

evaluation non-irritant

ethyl acetate

Species	rabbit		
Remarks	No effect of irritation known.		

(S)-p-mentha-1,8-diene

Remarks No data available.

Serious eye damage/irritation

Remarks Eye contact with the product may lead to irritation.

Serious eye damage/irritation (Components)**7-Methyl-3-methylenocta-1,6-dien**

Species	rabbit		
evaluation	irritant		

beta-Caryophyllen

Remarks No data available.

ethanol

evaluation irritant

ethyl acetate

evaluation strongly irritant

(S)-p-mentha-1,8-diene

Species	rabbit		
evaluation	non-irritant		
Method	OECD 405		
Remarks	No effect of irritation known		

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Sensitization (Components)**7-Methyl-3-methylenocta-1,6-dien**

Species	mouse
evaluation	non-sensitizing
Method	OECD 429

beta-Caryophyllen

Remarks	No data available.
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ethyl acetate

Species	guinea pig
evaluation	non-sensitizing
Method	OECD 406

(S)-p-mentha-1,8-diene

Species	mouse
evaluation	sensitizing
Method	OECD 429
Remarks	May cause sensitization by skin contact.

Subacute, subchronic, chronic toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks	Not applicable
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(S)-p-mentha-1,8-diene

Remarks	No data available.
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Mutagenicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Species	Salmonella typhimurium
evaluation	No mutagenicity in the Ames-test.
Method	Ames test

7-Methyl-3-methylenocta-1,6-dien

Species	mouse
evaluation	No mutagenicity in the micronucleus test.
Remarks	negative

beta-Caryophyllen

Remarks	No data available.
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ethanol

evaluation	No mutagenicity in the Ames-test.
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ethyl acetate

Species	Salmonella typhimurium
evaluation	No mutagenicity in the Ames-test.
Method	OECD 471
Remarks	negative

ethyl acetate

Species	mammal, species unspecified
Remarks	negative

(S)-p-mentha-1,8-diene

Species	mouse
Remarks	negative

(S)-p-mentha-1,8-diene

Species	rat (male)
Remarks	negative

Reproduction toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Species	rat
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evaluation	Can cause malformations.
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beta-Caryophyllen

Remarks	No data available.
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ethyl acetate

Remarks	No data available.
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(S)-p-mentha-1,8-diene

Remarks	No data available.
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Carcinogenicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks	No data available.
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ethyl acetate

Remarks	No data available.
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(S)-p-mentha-1,8-diene

Species	rat
Remarks	May cause cancer.
Source	RTECS

(S)-p-mentha-1,8-diene

Species	mouse
Remarks	Based on available data, the classification criteria are not met.
Source	RTECS

Specific Target Organ Toxicity (STOT) (Components)**beta-Caryophyllen**

Remarks	Not applicable
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ethyl acetate**Single exposure**

evaluation	Causes damage to organs. Route of exposure inhalative Organs: Nervous system
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(S)-p-mentha-1,8-diene

Remarks	Not applicable
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Aspiration hazard (Components)**beta-Caryophyllen**

Harmful: may cause lung damage if swallowed.
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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 (Components)****7-Methyl-3-methylenocta-1,6-dien**

Remarks	No data available.
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beta-Caryophyllen

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Remarks No data available.

Bornan-2-one

LC50	35		mg/l
Duration of exposure	96	h	

ethyl acetate

Species	Fathead minnow (<i>Pimephales promelas</i>)		
	230		mg/l
Duration of exposure	96	h	

(S)-p-mentha-1,8-diene

Species	Fathead minnow (<i>Pimephales promelas</i>)		
LC50	0.72		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Daphnia toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks No data available.

beta-Caryophyllen

Remarks No data available.

ethyl acetate

Species	Daphnia magna		
EC50	717		mg/l
Duration of exposure	48	h	

(S)-p-mentha-1,8-diene

Species	Daphnia magna		
	0.36		mg/l
Duration of exposure	48	h	

Algae toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks No data available.

beta-Caryophyllen

Remarks No data available.

ethyl acetate

Species	Desmodesmus subspicatus		
	3300		mg/l
Duration of exposure	48	h	

(S)-p-mentha-1,8-diene

Remarks No data available.

Bacteria toxicity (Components)**7-Methyl-3-methylenocta-1,6-dien**

Remarks No data available.

beta-Caryophyllen

Remarks No data available.

ethyl acetate

Species	Pseudomonas putida		
	2900		mg/l
Duration of exposure	16	h	

(S)-p-mentha-1,8-diene

Species	activated sludge		
EC50	3.94		mg/l
Method	OECD 209		

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12.2. Persistence and degradability

Physico-chemical eliminability (Components)

beta-Caryophyllen

Remarks No data available.

ethyl acetate

Remarks No data available.

(S)-p-mentha-1,8-diene

Remarks No data available.

Biodegradability (Components)

7-Methyl-3-methylenocta-1,6-dien

Value 76 %

Duration of test 28 d
evaluation Readily biodegradable

beta-Caryophyllen

Remarks No data available.

ethanol

evaluation Readily biodegradable

ethyl acetate

Value 100 %

Duration of test 28 d
evaluation Readily biodegradable
Method OECD 301D

(S)-p-mentha-1,8-diene

Value 71 %

evaluation Readily biodegradable

Ready degradability (Components)

7-Methyl-3-methylenocta-1,6-dien

beta-Caryophyllen

Remarks No data available.

ethyl acetate

(S)-p-mentha-1,8-diene

Chemical oxygen demand (COD) (Components)

ethanol

Value 0.93 to 1.67 mg/g

ethyl acetate

Value 1820 mg/g

Source Theoretischer Sauerstoffbedarf (ThSB)

(S)-p-mentha-1,8-diene

Remarks No data available.

Biochemical oxygen demand (BOD5) (Components)

(S)-p-mentha-1,8-diene

Remarks No data available.

12.3. Bioaccumulative potential

Octanol/water partition coefficient (log Pow) (Components)

7-Methyl-3-methylenocta-1,6-dien

log Pow 5.285
Temperature 25 °C

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ethyl acetatelog Pow 0.73
Method experimental**(S)-p-mentha-1,8-diene**

log Pow 4.2

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

BCF 0.66

12.5. Results of PBT and vPvB assessment**Evaluation of persistence and bioaccumulation potential**

The product contains no PBT or vPvB substances.

Evaluation of persistence and bioaccumulation potential (Components)**ethanol**

The Substance doesn't meet 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. 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

H225 Highly flammable liquid and vapour.
 H319 Causes serious eye irritation.
 H336 May cause drowsiness or dizziness.

CLP categories listed in Chapter 3

Eye Irrit. 2 Eye irritation, Category 2
 Flam. Liq. 2 Flammable liquid, Category 2
 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.