

Trade name: eingestellter Cannabisextrakt 5%

Substance number: 053200

Version: 3 / CH

Date revised: 26.06.2023

Replaces Version: 2 / CH

Print date: 26.06.23

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

1.1. Product identifier

eingestellter Cannabisextrakt 5%

Item No. 05320000

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

Use of the substance/preparation

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)

Repr. 2

H361fd

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

H361fd

Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary statements

P201

Obtain special instructions before use.

P280

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

P308+P313

IF exposed or concerned: Get medicinal advice/attention.

P405

Store locked up.

P501.3

Disposal in compliance with local and national regulations.

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

contains (6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

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 *****Chemical characterization**

Extract of herbal drugs

Hazardous ingredients *****(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol**

CAS No.	1972-08-3			
Concentration	>=	3	<	10 %
Classification (Regulation (EC) No. 1272/2008)				
	Acute Tox. 4			H302
	Repr. 2			H361

ATE	oral	482	mg/kg
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2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

CAS No.	13956-29-1			
EINECS no.	689-176-3			
Concentration	>=	0.1	<	1 %
Classification (Regulation (EC) No. 1272/2008)				
	Acute Tox. 4			H302
	Repr. 2			H361fd

Further ingredients *****Glycerides, mixed decanoyl and octanoyl**

CAS No.	73398-61-5			
EINECS no.	277-452-2			
Concentration	>=	25	<	50 %
Advice: [4]				

6-O-palmitoylascorbic acid

CAS No.	137-66-6			
EINECS no.	205-305-4			
Concentration			<	1 %
Advice: [4]				
Classification (Regulation (EC) No. 1272/2008)				
	Eye Irrit. 2			H319

Note

[4] Voluntary information

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

Poisonous symptoms can first be observed after several hours, therefore medical observation for at

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least 48 hours is necessary.

After inhalation

When spray fog inhaled, seek medical aid immediately and show the physician the packing or the packing label.

After skin contact

Wash off immediately with soap and water and rinse well. Consult a doctor if symptoms occur.

After eye contact

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. By continuous complaints consult a physician.

After ingestion

In the event of symptoms take medical treatment.

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

Extinguishing measures to suit surroundings

5.2. Special hazards arising from the substance or mixture

If a fire breaks out nearby evolution of dangerous gases possible.

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

Use self-contained breathing apparatus.

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

Use personal protective clothing. Do not inhale vapours. Ensure adequate ventilation.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

When picked up, treat material as prescribed under Section 13 "Disposal". Ensure adequate ventilation.

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8. Information regarding waste disposal, see Section 13.

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

Women of childbearing age and during lactation should avoid the contact with the product.

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

Keep only in original packaging. Store away from sources of ignition and heat. Keep container tightly closed in a well-ventilated place.

Hints on storage assembly

Do not store together with foodstuffs.

Storage classes

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Storage class according to TRGS 510 12

Non-combustible liquids

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work.

Respiratory protection

At intensive and longer exposition use self-contained breathing apparatus. Short term: filter apparatus

Hand protection

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Appropriate Material nitrile rubber - NBR

Hand protection must comply with EN 374.

Eye protection

Safety glasses

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state liquid

Colour yellow to brownish yellow

Boiling point or initial boiling point and boiling range

Remarks No data available

Flash point

Value °C

Remarks Not applicable

Vapour pressure

Remarks not determined

Density and/or relative density

Value 0.951 to 0.955

Remarks Relative Density according specification

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Strong oxidising agents

10.6. Hazardous decomposition products

Formation of toxic gases possible during heating or in case of fire.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

ATE	8'763.63 64	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Species	rat	
LD50	666	mg/kg

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Species	mouse	
LD50	482	mg/kg

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Species	dog	
LD50	> 3000	mg/kg

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Species	monkey	
LD50	> 3150	mg/kg

6-O-palmitoylascorbic acid

Species	rat	
LD50	> 10000	mg/kg

6-O-palmitoylascorbic acid

Species	mouse	
LD50	25000	mg/kg

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

Species	Human	
TDLO	5.63	mg/kg

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

Species	mouse	
LD50	> 750	mg/kg

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

Species	monkey	
LD50	> 300	mg/kg

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

Species	Human	
LD50	> 20	mg/kg

Acute dermal toxicity (Components)

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Remarks	No data available.
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6-O-palmitoylascorbic acid

Species	guinea pig	
LD50	> 3000	mg/kg

Acute inhalative toxicity (Components)

(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol

Remarks	No data available.
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6-O-palmitoylascorbic acid

Remarks	No data available.
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Skin corrosion/irritation (Components)**(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol**

Remarks No data available.

6-O-palmitoylascorbic acidSpecies rabbit
evaluation slightly irritant**Serious eye damage/irritation (Components)****(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol**

Remarks No data available.

6-O-palmitoylascorbic acidSpecies rabbit
evaluation irritant
Method Draize method**Sensitization (Components)****(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol**

Remarks No data available.

6-O-palmitoylascorbic acidevaluation non-sensitizing
Remarks No sensitisation effect known.**Subacute, subchronic, chronic toxicity (Components)****6-O-palmitoylascorbic acid**

Remarks Not applicable

Mutagenicity (Components)**6-O-palmitoylascorbic acid**

Remarks negative

Reproduction toxicity (Components)**6-O-palmitoylascorbic acid**

evaluation No negative effects

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)Route of exposure oral
Species mouse
Dose 50 mg/kg
evaluation Suspected of damaging fertility. Suspected of damaging the unborn child.**Carcinogenicity (Components)****6-O-palmitoylascorbic acid**

Remarks negative

Specific Target Organ Toxicity (STOT) (Components)**6-O-palmitoylascorbic acid**

Remarks Not applicable

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.

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

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Fish toxicity (Components)**6-O-palmitoylascorbic acid**

Species	Salmo gairdneri	
LC50	51	mg/l
Duration of exposure	96	h

Daphnia toxicity (Components)**6-O-palmitoylascorbic acid**

Remarks No data available.

Algae toxicity (Components)**6-O-palmitoylascorbic acid**

Remarks No data available.

Bacteria toxicity (Components)**6-O-palmitoylascorbic acid**

Remarks No data available.

12.2. Persistence and degradability**Physico-chemical eliminability (Components)****6-O-palmitoylascorbic acid**

Remarks No data available.

Biodegradability (Components)**6-O-palmitoylascorbic acid**

Value	48	%
Duration of test evaluation	28	d
Method	not readily degradable OECD 302B/ISO 9888/EEC 88/302,C	

Ready degradability (Components)**6-O-palmitoylascorbic acid**

Method	OECD 302B/ISO 9888/EEC 88/302,C
Remarks	Not readily biodegradable.

12.3. Bioaccumulative potential**Octanol/water partition coefficient (log Pow) (Components)****6-O-palmitoylascorbic acid**

log Pow	6.0
Method	calculated

2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (Cannabidiol)

pOW	126000	to	214000
	0		0

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

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13.1. Waste treatment methods**Disposal recommendations for the product**

Do not dispose of it with household waste.
Do not allow to enter drains or water courses.
Dispose of waste according to applicable legislation.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	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

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.
H361 Suspected of damaging fertility or the unborn child.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4
Repr. 2 Reproductive toxicity, Category 2

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.