

Trade name: Stammlösung für raffiniertes Cannabisölharz nach DAC (> 5% THC)

Substance number: 053190

Version: 2 / CH

Date revised: 26.06.2023

Replaces Version: 1 / CH

Print date: 26.06.23

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

1.1. Product identifier

Stammlösung für raffiniertes Cannabisölharz nach DAC (> 5% THC)

Item No. 05319000

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 *****3.2. Mixtures****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 | >= | 10 | < | 24 % |
| Classification (Regulation (EC) No. 1272/2008) | | | | |
| | Acute Tox. 4 | | H302 | |
| | Repr. 2 | | H361 | |

| | | | |
|-----|------|-----|-------|
| ATE | oral | 482 | mg/kg |
|-----|------|-----|-------|

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 | >= | 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**

Trade name: Stammlösung für raffiniertes Cannabisölharz nach DAC (> 5% THC)

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General information

Poisonous symptoms can first be observed after several hours, therefore medical observation for at least 48 hours is necessary.

After inhalation

Remove to fresh air, keep patient warm and at rest. In the event of symptoms take medical treatment. If the patient is likely to become unconscious, place and transport in stable sideways position. Take medical treatment.

After skin contact

Wash off immediately with soap and water and rinse well.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Rinse mouth thoroughly with water. Do NOT induce vomiting. 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**

Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid contact with skin and eyes. Avoid formation of aerosols. Keep away from heat and sources of ignition. Smoking, eating and drinking should be prohibited in application area.

7.2. Conditions for safe storage, including any incompatibilities**Recommended storage temperature**

| | | | |
|-------|---|----|----|
| Value | 2 | 25 | °C |
|-------|---|----|----|

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Replaces Version: 1 / CH

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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

Storage class according to TRGS 510 12 Non-combustible liquids

Further information on storage conditions

Protect from light. Keep containers tightly closed in a dry, cool and well-ventilated place.

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 | greenish yellow |
| Colour | brown |

Boiling point or initial boiling point and boiling range

| | |
|---------|-------------------|
| Remarks | No data available |
|---------|-------------------|

Flash point

| | |
|---------|----------------|
| Value | °C |
| Remarks | Not applicable |

Vapour pressure

| | |
|---------|----------------|
| Remarks | Not applicable |
|---------|----------------|

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.

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Substance number: 053190

Version: 2 / CH

Date revised: 26.06.2023

Replaces Version: 1 / CH

Print date: 26.06.23

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.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

| | | |
|-----|----------|-------|
| ATE | 4'257.95 | mg/kg |
| | 05 | |

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.

6-O-palmitoylascorbic acid

Species guinea pig

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Substance number: 053190

Version: 2 / CH

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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.

6-O-palmitoylascorbic acid

Remarks No data available.

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**

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The product does not contain a substance that has endocrine disrupting properties with respect to humans.

SECTION 12: Ecological information ***

12.1. Toxicity

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.

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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

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.