

Trade name: Dronabinol

Substance number: 051850

Version: 3 / CH

Date revised: 11.09.2020

Replaces Version: 2 / CH

Print date: 11.09.20

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

### **1.1. Product identifier**

Dronabinol

Item No. 05185000

#### **Substance / product identification**

CAS-No. 1972-08-3

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

#### **Use of the substance/preparation**

Raw material for pharmaceutical production and analysis

### **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)

Acute Tox. 4 H302

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 \*\*\***

H302 Harmful if swallowed.

H361 Suspected of damaging fertility or the unborn child.

#### **Precautionary statements \*\*\***

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P201 Obtain special instructions before use.  
 P264.1 Wash hands thoroughly after handling.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P308+P313 IF exposed or concerned: Get medicinal advice/attention.  
 P330 Rinse mouth.  
 P501.3 Disposal in compliance with local and national regulations.

**Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)**contains \*\*\* 1-Trans- $\Delta$ 9-Tetrahydrocannabinol**SECTION 3: Composition/information on ingredients \*\*\*****Chemical characterization**

Dronabinol

**Molecular weight**

Value 314.47 g/mol

**Hazardous ingredients \*\*\*****1-Trans- $\Delta$ 9-Tetrahydrocannabinol**

CAS No. 1972-08-3

Concentration  $\geq$  50 %

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

Acute Tox. 4 H302

Repr. 2 H361

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

In case of accident or if you feel unwell, seek medical advice immediately. In any case show the physician the Safety Data Sheet.

**After inhalation \*\*\***

Remove to fresh air, keep patient warm and at rest. If necessary, device ventilation or oxygen supply. Summon a doctor immediately.

**After skin contact**

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

**After eye contact**

Remove contact lenses, irrigate copiously with clean, fresh water, holding the eyelids apart for at least 10 minutes and seek immediate medical advice.

**After ingestion**

Rinse mouth thoroughly with water. Summon a doctor immediately. Turn a vomiting person lying on his back onto his side. Provide for body rest, protect against loss of heat.

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

Comprehensive and diverse effects on the psyche: Euphoria, Hallucinations, amnesia, Other symptoms: Hypothermia, Drowsiness, Nausea, Headache, Vomiting

**4.3. Indication of any immediate medical attention and special treatment needed****Hints for the physician / treatment**

Treat symptomatically

**SECTION 5: Firefighting measures**

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## 5.1. Extinguishing media

### Suitable extinguishing media

Carbon dioxide, Foam, Dry chemical extinguisher, Water spray jet

### Non suitable extinguishing media

Full water jet

## 5.2. Special hazards arising from the substance or mixture

The product is combustible. Avoid inhalation of smoke and vapours. Carbon dioxide (CO<sub>2</sub>); Carbon monoxide (CO)

## 5.3. Advice for firefighters

### Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Wear protective clothing.

### Other information

Do not discharge into surface waters/groundwater.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin. Wear protective equipment. Do not inhale vapours. Ensure adequate ventilation.

### 6.2. Environmental precautions

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). Take up mechanically and collect in suitable container for disposal.

### 6.4. Reference to other sections

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

Wear protective equipment. Avoid contact with skin and eyes. Avoid inhaling dusts/ billows/ steams. Ensure adequate ventilation. Smoking, eating and drinking should be prohibited in application area.

#### Advice on protection against fire and explosion

Keep away from ignition sources, fire and open light.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep under lock and key. Keep in a dry place. Keep container tightly closed in a well-ventilated place. Store at room temperature. Protect from exposure to light.

#### Hints on storage assembly

Do not store together with foodstuffs. Do not store together with animal feedstocks. Do not store with strong oxidizing agents.

#### Storage classes \*\*\*

Storage class according to TRGS 510      10      Flammable liquids

#### Further information on storage conditions

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Prevent unauthorised access. The requirements for storage rooms should be in line with those prescribed by the narcotics law.

## **SECTION 8: Exposure controls/personal protection \*\*\***

### **8.1. Control parameters**

#### **Other information**

Contains no substances with occupational exposure limit values.

### **8.2. Exposure controls**

#### **Exposure controls**

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction.

#### **General protective and hygiene measures**

Do not inhale vapours. Do not eat, drink or smoke during work time. Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work.

#### **Respiratory protection**

If vapours occur, use filter type A (= against vapours of organic compounds) according to EN 14387.

#### **Hand protection**

Appropriate Material	Butyl rubber - Butyl
Breakthrough time	> 480 min
Hand protection must comply with EN 374.	

#### **Eye protection**

Eye protection must comply with EN 166.

#### **Body protection**

Clothing as usual in the chemical industry.

## **SECTION 9: Physical and chemical properties \*\*\***

### **9.1. Information on basic physical and chemical properties**

<b>Form</b>	Solidified resin
<b>Colour</b>	light to yellowish
<b>Odour</b>	odourless
<b>Odour threshold</b>	
Remarks	No data available
<b>pH value</b>	
Remarks	No data available
<b>Melting point</b>	
Remarks	No data available
<b>Freezing point</b>	
Remarks	No data available
<b>Initial boiling point and boiling range</b>	
Value	220 °C
Pressure	0.02 hPa
<b>Flash point</b>	
Value	°C
Remarks	Not applicable
<b>Evaporation rate</b>	
Remarks	No data available

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**Flammability (solid, gas) \*\*\***

No data available

**Upper/lower flammability or explosive limits**

Remarks No data available

**Vapour pressure**

Remarks No data available

**Vapour density**

Remarks No data available

**Density**

Value 0.91 to 1.00 g/ml

**Solubility in water**

Value 4 mg/l

Temperature 23 °C

**Solubility(ies) \*\*\***

fat oils

Remarks easily soluble

**Partition coefficient: n-octanol/water****Dronabinol**

pOW 6.97

Remarks Due to the distribution coefficient n-octanol/water, accumulation in organisms is possible.

**Auto-ignition temperature**

Remarks No data available

**Decomposition temperature**

Remarks No data available

**Viscosity**

Remarks No data available

**Explosive properties**

evaluation No data available

**Oxidising properties**

Remarks No data available

**9.2. Other information****Dissociation constant**

Value 10.6

**SECTION 10: Stability and reactivity \*\*\*****10.1. Reactivity**

Do not store with combustible materials.

**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**

Keep away from sources of heat and ignition. Protect from light.

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**10.5. Incompatible materials**

Reactions with oxidising agents.

**10.6. Hazardous decomposition products**

No hazardous decomposition products known when handled according to prescribed instructions.

**SECTION 11: Toxicological information \*\*\*****11.1. Information on toxicological effects****Acute oral toxicity****Dronabinol**

ATE	482.048	mg/kg
	2	
Method	calculated value (Regulation (EC) No. 1272/2008)	

**Acute oral toxicity (Components)****1-Trans- $\Delta$ 9-Tetrahydrocannabinol**

Species	rat		
LD50	666	mg/kg	

**1-Trans- $\Delta$ 9-Tetrahydrocannabinol**

Species	mouse		
LD50	482	mg/kg	

**1-Trans- $\Delta$ 9-Tetrahydrocannabinol**

Species	dog		
LD50	> 3000	mg/kg	

**1-Trans- $\Delta$ 9-Tetrahydrocannabinol**

Species	monkey		
LD50	> 3150	mg/kg	

**Skin corrosion/irritation****Dronabinol**

Remarks No data available.

**Serious eye damage/irritation****Dronabinol**

Remarks No data available.

**Sensitization****Dronabinol**

Remarks No data available.

**Carcinogenicity****Dronabinol**

Remarks No data available.

**Specific Target Organ Toxicity (STOT)****Dronabinol**

Remarks No data available.

**Aspiration hazard****Dronabinol**

No data available.

**Other information**

Use can lead to psychological dependence.

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

May cause long lasting harmful effects to aquatic life.

**12.2. Persistence and degradability****General information**

No data available

**12.3. Bioaccumulative potential****Partition coefficient: n-octanol/water****Dronabinol**

pOW

6.97

Remarks

Due to the distribution coefficient n-octanol/water, accumulation in organisms is possible.

**12.4. Mobility in soil****General information**

No data available

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

No data available

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

Do not allow it to reach soil, ground water, water bodies or sewage system.

**General information / ecology**

Ecological injuries are not known or expected under normal use.

**SECTION 13: Disposal considerations \*\*\*****13.1. Waste treatment methods****Disposal recommendations for the product**

EWC waste code 18 01 06\* chemicals consisting of or containing dangerous substances  
Residues of the product must be destroyed in accordance with the provisions of the narcotics act and a protocol must be drawn up.  
Incineration with official authorisation.

**Disposal recommendations for packaging \*\*\***

EWC waste code 15 01 10\* packaging containing residues of or contaminated by dangerous substances

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
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

### **15.2. Chemical safety assessment**

For this substance a chemical safety assessment has not been carried out.

## **SECTION 16: Other information**

### **Hazard statements listed in Chapter 3**

H302      Harmful if swallowed.

H361      Suspected of damaging fertility or 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.