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Print Date 01.08.2019

# Material Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Dronabinol, API



#### 1 Identification of the substance/mixture and of the company/undertaking

- · Informations to product No. 4854
- · Product name:

# Dronabinol, API

· Supplier of the Product / responsible Company:

Caesar & Loretz GmbH Herderstr. 31 40721 Hilden

Tel.: 02103/4994-0 Fax: 02103/32360 e-mail: info@caelo.de • Emergency telephone: Giftinformationszentrum Mainz Langenbeckstr. 1, 55131 Mainz

Tel.: 06131/19240

· Relevant identified uses of the substance or mixture and uses advised against:

No further relevant information available.

· Application of the substance / mixture:

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

#### 2 Hazards identification

· GHS-Labelling Elements:



· Signal word: Warning

· H-Phrases:

H302 Harmful if swallowed

H361 Suspected of damaging fertility or the unborn child

· P-Phrases:

P201 Obtain special instructions before use

P280 Wear protective gloves/protective clothing/eye protection/face protection

P308 IF exposed or concerned

P313 Get medical advice/attention

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#### 3 Composition / information on ingredients

#### CAS-No. Substance name

1972-08-3 Dronabinol • **EINECS-No.:** 625-153-6

- · REACH Reg. No.: -
- · INCI-Name: -
- · Chemical characterization:

#### 4 First aid measures

- after inhalation: Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- after skin contact: Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- after eye contact: Rinse out with plenty of water with the eyelid wide open. Call in ophthalmologist.
- after swallowing: Drink plenty of water. Induce vomiting. Seek medical advice immediately.

#### 5 Fire-fighting measures

- Suitable extinguishing media: All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- Specific hazards during fire fighting: Combustible but not flammable. In case of fire dangerous gases / vapours can be released: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- Additional information: Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

#### 6 Accidental release measures:

- Personal protective measures: Avoid contact with substance.
- Environmental protective measures: Prevent from entering into surface water, the ground water system or soil.
- Methods for cleaning: Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

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# 7 Handling and storage

- · Handling:
- · Advice on safe handling: Wear protective equipment (See chapter 8).
- Storage:
- Requirements for storage areas and containers: Tightly closed. Store at a dry place. At room temperature (15°C to 25°C). Protect from light.
- · Advices on common storage: Not required.

## 8 Exposure controls / personal protective equipment

- · Personal protective equipment:
- · General protective and hygiene measures:

Keep away from food, beverages and animal food.

Wash hands before breaks and after work.

- · Respiratory protection: Dust protection mask.
- · Hand protection: Protection gloves of latex or rubber.
- · Eye protection: Safety glasses.

## 9 Physical and chemical properties

- Form: highly viscous resin
- · Colour: white crystalline powder
- · Odour: faint, aromatic
- Melting point / melting range: not determined
   Boiling point / boiling range: 155 157 °C (6,5 Pa)
- · Solubility in / Miscibility with
- Water: (20 °C) ca. 0,003 g/l
- · pH-range: neutral

#### 10 Stability and reactivity

#### Hazardous decomposition products:

At high temperatures irritant or harmful vapours are released.

#### 11 Toxicological information

· Acute toxicity:

LD50, mouse, oral: 482 mg/kg LD50 mouse, i.v.: 42 mg/kg LD50 rat, oral: 666 mg/kg LD50 rat, i.v.: 29 mg/kg

Toxity values in the literature are very different.

Primary irritant effect:
on skin: Slightly irritant.
on eyes: Slightly irritant.

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## 12 Ecological information

· Ecotoxical effects:

Quantitative ecotoxicological data for this product are not available.

- · General advices: Prevent from leaking into ground water, environment waters or drainage.
- Water hazard class: 1 (self classification): slightly hazardous for water.

#### 13 Disposal considerations

- · Product:
- · Recommendation: Disposal according to local regulations as pharmaceutical waste.
- · Empty contaminated packaging:
- · Recommendation: Disposal according to the local regulations.

#### 14 Transport informations

· Land transport according to ADR:

Not classified as dangerous in the meaning of transport regulations.

#### 15 Regulatory information

• Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):

The product is classified and labelled according to GHS-regulations.

- · Hazard symbols: GHS08, GHS07
- · Signal word: Danger
- · H-Phrases:

H302 Harmful if swallowed

H361 Suspected of damaging fertility or the unborn child

P-Phrases:

P201 Obtain special instructions before use

P280 Wear protective gloves/protective clothing/eye protection/face protection

P308 IF exposed or concerned

P313 Get medical advice/attention

- · National regulations (Germany):
- · Water hazard class: see chapter 12
- · Storage class TRGS 510: 6.1C

#### 16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

• Reason for last revision: Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.