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Print Date 29.11.2018

Material Safety Data Sheet according to Regulation (EC) No.

according to Regulation (EC) N 1907/2006 (REACH)

HILDANUS ®



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

- · Informations to product No. 7253
- · Product name:

HILDANUS ® Hildanus Magenbitter

· 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: Spirituous liquor.
- · Application of the substance / mixture:

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

2 Hazards identification

• **Hazards identification:** The substance is not classified as dangerous according to European Union legislation.

3 Composition / information on ingredients

• Chemical characterization: Mixture of different alcoholic plant extracts.

CAS-No. Substance name 64-17-5 Ethanol (ca.50% (V/V))

• **EINECS-No.:** 200-578-6

· REACH-No.: 01-2119457610-43-0010

· INCI-Name: Alcohol

4 First aid measures

· after inhalation: Fresh air.

· after skin contact: Wash away with water and soap.

• after eye contact: Rinse out with plenty of water with the eyelid wide open.

· after swallowing: Not relevant (Alcoholic beverage).

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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. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- 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: No special measures required..
- Environmental protective measures: Do not empty into drains, prevent from contaminating surface water or the ground water system.
- **Methods for cleaning:** Absorb with liquid-binding material: Sand, silica gel, acid binder, universal binder, saw dust.

7 Handling and storage

- · Handling: No special requirements.
- **Informations to fire or explosion protection:** Keep away from ignition sources. Do not smoke.. Take measures to prevent electrostatic charging.
- · Storage:
- Requirements for storage areas and containers: Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- · Advices on common storage: Not required.
- · Additional informations to storage conditions: Keep container tightly closed.

8 Exposure controls / personal protective equipment

Components with limit values that require monitoring at the workplace: AGW(TRGS 900):

Ethanol (CAS: 64-17-5), 46-53% (V/V)

960 mg/m³, 500 ml/m³ 1900 mg/m³, 1000 ml/m³

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

Wash hands before breaks and after work.

- · Respiratory protection: Not required.
- · Hand protection: Not required.
- · Eye protection: Safety glasses.

9 Physical and chemical properties

Form: liquidColour: brown

· Odour: aromatic / alcoholic

· Melting point / melting range: not determined

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· Boiling point / boiling range: not determined

· Flash point: ca. 40 °C

Density: (20 °C) ca. 0,95 g/cm³
 Solubility in / Miscibility with

· Water: Completely miscible, essential oils might precipitate.

10 Stability and reactivity

- Thermical decomposition / conditions to avoid: No decomposition during appropriate use.
- · Materials to avoid: Oxidants
- · Hazardous reactions: No hazardous reactions known.
- · Hazardous decomposition products: none

11 Toxicological information

· Acute toxicity (Ethanol):

LD50(oral, Rat): 6200 mg/kg (IUCLID) LD50(oral, Rabbit): 6300 mg/kg LD50(oral, Guinea pig): 5560 mg/kg

LD50(oral, Mouse): 8350 mg/kg (OECD 401)

· Primary irritant effect:

on skin: Not irritant (OECD 404)on eyes: Irritant (OECD 405)

on respiratory organs: Slightly irritant.
Sensitization: no sensitizing effect known.

- Sub-acute / chronic toxicity: repeated exposition can cause neuronal damage. These effects were observed only at high dosage. Mutagentiy: Not mutagen.
- Additional toxicological informations: High concentrations can cause fatigue, vertigo or inconsciousness. Vapours and liquid can cause eye irritations.

12 Ecological information

· Information about elimination (persistence and degradability):

Readily biodegradable. Rapid photochemical oxidation in air.

- **Mobility and bioaccumulation potential:** Soluble in water. Disappears within one day by evaporation and dissolution. No substancial bioaccumulation. If big quantities are released, the product can penetrate into soil and have harmful effect on ground water.
- Aquatic toxicity: (Ethanol)

Fish toxicity:

LC50: 11200 mg/l/24h (Oncorhynchus mykiss, US EPA E03-05) LC50: 13000 mg/l/96h (Oncorhynchus mykiss, OECD 203)

Daphnia toxicity:

LC50: 12340 mg/l/48h (Daphnia magna, ASTM E729-80)

Water plants:

EC50: 275 mg/l/72h (Chlorella vulgaris, OECD 201) EC10: 12 mg/l/72h (Chlorella vulgaris, OECD 201)

Bacteria (Pseudomonas putida): Toxic concentration limit: 6500 mg/l

Activated sludge: Damage above 15g Ethanol/l • Behaviour in sewage plants: EC50: > 1000 mg/l.

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· General advices: Prevent from entering sewage water or drainage ditch undiluted or unneutralized.

• 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 does not need to be labelled according to GHS-regulations.

· National regulations (Germany):

· Water hazard class: see chapter 12

· Storage class TRGS 510: 10

· VbF class: B

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.