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

· **Informations to product No. g43**

· **Product name:**

Extractum Belladonnae sicc. normatum, API Eingestellter Belladonnablättertrockenextrakt

· **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-Labeling Elements:**



· **Signal word:** Warning

· **H-Phrases:**

H302 Harmful if swallowed.

· **P-Phrases:**


P301 IF SWALLOWED:

P312 Call a POISON CENTER or doctor/physician if you feel unwell

Acute Tox. 4

3 Composition / information on ingredients

· **Chemical characterization:** Dried extract from belladonna leafs, normated with lactose.

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CAS-No. Substance name

8007-93-0 Belladonna extract

- **EINECS-No.:** 232-365-9
- **REACH Reg. No.:** Exempted from the obligation to register according to Annex 4 / 5 REACH-regulation.
- **INCI-Name:** -

CAS-No. Substance name

10039-26-6 Lactose

- **EINECS-No.:** 200-559-2
- **REACH Reg. No.:** Exempted from the obligation to register according to Annex 4 / 5 REACH-regulation.
- **INCI-Name:** Lactose

CAS-No. Substance name

101-31-5 Hyoscyamin (1 %), GHS06, H300, H330

- **EINECS-No.:** 202-933-0
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -

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.
- **after swallowing:** Do not induce vomiting, assure medical help 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 dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **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:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.
- **Storage:**
- **Requirements for storage areas and containers:** Keep container tightly closed. Good ventilated. At room temperature. Accessible only for professional persons.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties

- **Form:** solid
- **Colour:** brown
- **Odour:** characteristic
- **Melting point / melting range:** not determined
- **Flash point:** not applicable
- **Density:**
- **Bulk density:** 500 - 600 kg/m³
- **Solubility in / Miscibility with**
- **Water:** soluble
- **pH-range:** (20 °C, 1%) ca. 5,4

10 Stability and reactivity


- **Hazardous decomposition products:** At high temperatures harmful vapours are released.

11 Toxicological information

- **Acute toxicity:**
Quantitative toxicological data for this product are not available. The classification is based on the concentration of Hyoscyamine.

12 Ecological information

- **Ecotoxical effects:**
Quantitative ecotoxicological data for this product are not available.
Prevent from leaking into ground water, environment waters or drainage.
- **Water hazard class:** 1 (self classification): slightly hazardous for water.

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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:** GHS07
- **Signal word:** Warning
- **H-Phrases:**
H302 Harmful if swallowed.
- **P-Phrases:**
P301 IF SWALLOWED:
P312 Call a POISON CENTER or doctor/physician if you feel unwell
- **National regulations (Germany):**
- **Water hazard class:** see chapter 12
- **Storage class TRGS 510:** 11

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.