


Page 1 of 5  Print Date 03.12.2018	<b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)  Tinctura Consolidae e Radice (70%) 1:5	 Revision Date 03.12.2018
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## 1 Identification of the substance/mixture and of the company/undertaking

- Informations to product No. g287a
- Product name:

### **Tinctura Consolidae e Radice (70%) 1:5** Beinwellwurzeltinktur (Pyrrolizidinalkaloid gereinigt) Comfrey root tincture (purified from pyrrolizidine alkaloides)

- 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:

H226 Flammable liquid and vapour

- P-Phrases:

P211 Do not spray on an open flame or other ignition source


**Flam. Liq. 3**

## 3 Composition / information on ingredients

- Chemical characterization:

**CAS-No. Substance name**

84696-05-9 Symphytum Officinale Extract

<p>Page 2 of 5</p> <p>Print Date 03.12.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Tinctura Consolidae e Radice (70%) 1:5</p>	 <p>Revision Date 03.12.2018</p>
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- **EINECS-No.:** 283-625-3
- **REACH Reg. No.:** Exempted from the obligation to register according to Annex 4 / 5 REACH-regulation.
- **INCI-Name:** Symphytum Officinale Extract

**CAS-No. Substance name**

64-17-5 Ethanol (67% (V/V)) GHS02, H226

- **EINECS-No.:** 200-578-6
- **REACH Reg. No.:** 01-2119457610-43-0010
- **INCI-Name:** Alcohol

**CAS-No. Substance name**

7732-18-5 Water (ad 100%)

- **EINECS-No.:** 231-791-2
- **REACH Reg. No.:** Exempted from the obligation to register according to Annex 4 / 5 REACH-regulation.
- **INCI-Name:** Aqua

#### 4 First aid measures


- **After inhalation:** Fresh air. If irritation of respiratory ways continues, seek medical advice.
- **After skin contact:** Take off contaminated clothes and shoes, wash away with plenty of water.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **After swallowing:** Drink water. Induce vomiting. If feeling unwell seek medical advice.

#### 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. Vapours are heavier / denser than air and spread on floor. Ignition over distances possible.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Cool endangered containers with water. Combustible liquid.

#### 6 Accidental release measures:

- **Personal protective measures:** Good ventilation of working place. Do not inhale vapours. Avoid contact with substance. Keep away from ignition sources. Do not smoke.
- **Environmental protective measures:** Prevent substance from entering into drainage ditch, surface waters, ground water and flowing waters.
- **Methods for cleaning:** Absorb with liquid-binding material: Sand, silica gel, acid binder, universal binder, saw dust. Disposal according to Chapter 13 of this MSDS. Clean up with water.

<p>Page 3 of 5</p> <p>Print Date 03.12.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Tinctura Consolidae e Radice (70%) 1:5</p>	 <p>Revision Date 03.12.2018</p>
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## 7 Handling and storage

- **Handling:**
- **Advice on safe handling:** Remove all open flames or ignition sources. Do not smoke. Good ventilation of working place. Prevent from entering into drains.
- **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:** Store at a cool and good ventilated place. Keep container tightly closed. Protect from direct sunlight and other heat- or ignition sources.
- **Advices on common storage:** Do not store together with oxidants, self-igniting substances or flammable solids.
- **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), 67% (V/V)

960 mg/m<sup>3</sup>, 500 ml/m<sup>3</sup>

1900 mg/m<sup>3</sup>, 1000 ml/m<sup>3</sup>

• **General protective and hygiene measures:**

Wash hands before breaks and after work.

Do not inhale vapours.

Avoid contact with eyes and skin.


• **Respiratory protection:** Good ventilation / exhaustion of working place.

• **Hand protection:** Protection gloves of PVC or rubber.

• **Eye protection:** Safety glasses.

## 9 Physical and chemical properties

- **Form:** liquid
- **Colour:** light brown to dark brown
- **Odour:** alcoholic / aromatic
- **Melting point / melting range:** Not determined.
- **Boiling point / boiling range:** above 80 °C
- **Flash point:** ca. 40 °C
- **Ignition temperature:** 425 °C (Ethanol vapour)
- **Explosion hazard:** The product is not explosive, but explosive mixtures of vapour with air can be formed.
- **Explosion limits (Ethanol):**
- **lower:** 3 Vol %
- **upper:** 15 Vol %
- **Solubility in / Miscibility with**
- **Water:** completely miscible.
- **pH-range:** neutral

<p>Page 4 of 5</p> <p>Print Date 03.12.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Tinctura Consolidae e Radice (70%) 1:5</p>	 <p>Revision Date 03.12.2018</p>
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## 10 Stability and reactivity


- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Hazardous reactions:** Reactions with oxidants and strong acids.
- **Hazardous decomposition products:** Acetaldehyde after reaction with strong oxidants.

## 11 Toxicological information

- **Acute toxicity (Ethanol):**  
**LD/LD50-data relevant for hazard classification:**  
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 irritating 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. Mutagenity: Not mutagen.
- **Additional toxicological informations:** High concentrations can cause fatigue, vertigo or unconsciousness. 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 substantial bioaccumulation. If big quantities are released, the product can penetrate into soil and have harmful effect on ground water.
- **Aquatic toxicity:**
  - 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.
- **General advices:** Prevent from entering sewage water or drainage ditch undiluted or unneutralized.
- **Water hazard class:** 1 (VwVwS): slightly hazardous for water.

<p>Page 5 of 5</p> <p>Print Date 03.12.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Tinctura Consolidae e Radice (70%) 1:5</p>	 <p>Revision Date 03.12.2018</p>
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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. Empty container completely and let evaporate residues in a safe place.

### 14 Transport informations

- **Land transport according to ADR:**
- **Proper shipping name:** Tinctures, medical
- **Class:** 3
- **UN-number:** 1293
- **Packing group:** III
- **Classification code:** F1
- **Limited quantities (Table 3.4.6. ADR):** 5 Liter
- **Hazard classification number:** 30
- **Special provisions (Chapter 3.3 ADR):** -
- **Additional informations for sea transport IMDG:**
- **EMS-No.:** F-E, S-D
- **Properties:** Fp=40°C

### 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:** GHS02
- **Signal word:** Warning
- **Signal word:** Warning
- **H-Phrases:**  
H226 Flammable liquid and vapour
- **P-Phrases:**  
P211 Do not spray on an open flame or other ignition source
- **National regulations (Germany):**
- **Water hazard class:** see chapter 12
- **Storage class TRGS 510:** 3
- **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.