



Safety data sheet according to 1907/2006/EC, Article 31

Printing date 08.10.2021

Version number 1.00

Revision: 06.10.2021

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

- **Product identifier**
- **Trade name:** Belladonna leaf dry extract, standardised
- **Article number:** G43
- **Registration number** The substance is exempt from REACH-registration.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- **Uses advised against** No relevant information available.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY
- **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
- **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 4 H302 Harmful if swallowed.
Acute Tox. 4 H332 Harmful if inhaled.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**
H302+H332 Harmful if swallowed or if inhaled.

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· Precautionary statements

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read carefully and follow all instructions.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 Wash thoroughly after handling.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P330 Rinse mouth.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Other hazards**· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Mixtures

- **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

- | | | |
|--|-------------|------|
| CAS: 101-31-5 | hyoscyamine | 1.0% |
| EINECS: 202-933-0 Acute Tox. 2, H300; Acute Tox. 2, H330 | | |
| CAS: 64-17-5 | ethanol | 0.5% |
| EINECS: 200-578-6 Flam. Liq. 2, H225 | | |

· Non-hazardous components

- CAS: 10039-26-6 Lactose
- 8007-93-0 Belladonna ext.

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

· Description of first aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** CO₂, powder or water spray. Fight larger fire with alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Combustible. Vapors are heavier than air and spread on the ground. Ignition possible over distance.
- **Advice for firefighters**
- **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
- **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Protect from heat and direct sunlight.
- **Storage class:** TRHS 510: 3 Flammable liquid
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

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- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
CAS: 64-17-5 ethanol
AGW (Germany) Long-term value: 380 mg/m³, 200 ppm
4(II);DFG, Y
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Respiratory protection or good ventilation of working place.
- **Protection of hands:** Protective gloves
- **Material of gloves**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Tightly sealed goggles

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Colour:	Brown
Odour:	Alcohol-like
Odour threshold:	Not determined.
pH-value:	Not determined. Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** 425 °C
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.

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· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	3 Vol %
Upper:	15 Vol %
· Vapour pressure:	Not determined. Not applicable.
· Density:	Not determined.
· Bulk density:	500–600 kg/m ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined. Not applicable.
Kinematic:	Not determined. Not applicable.
· Solvent content:	
Organic solvents:	0.5 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
 - **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
 - **Possibility of hazardous reactions**
Reacts with oxidising agents.
Reacts with strong acids.
 - **Conditions to avoid** No further relevant information available.
 - **Incompatible materials:** No further relevant information available.
 - **Hazardous decomposition products:** Acetaldehyde after reaction with strong oxidants
-

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Harmful if swallowed or if inhaled.

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· LD/LC50 values relevant for classification:**CAS: 64-17-5 ethanol**

Oral LD50 7,060 mg/kg (rat)

Inhalative LC50 20,000 mg/m³ (rat)**· Primary irritant effect:****· Skin corrosion/irritation** Based on available data, the classification criteria are not met.**· Serious eye damage/irritation** Based on available data, the classification criteria are not met.**· Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**· Additional toxicological information:****· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)****· Germ cell mutagenicity** Based on available data, the classification criteria are not met.**· Carcinogenicity** Based on available data, the classification criteria are not met.**· Reproductive toxicity** Based on available data, the classification criteria are not met.**· STOT-single exposure** Based on available data, the classification criteria are not met.**· STOT-repeated exposure** Based on available data, the classification criteria are not met.**· Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

· Toxicity**· Aquatic toxicity:****CAS: 64-17-5 ethanol**

LC50 14,200 mg/L (Fish)

EC50 275 mg/L (Algae)

5,000 mg/L (invertebrates)

5,800 mg/L (Microorganism)

· Persistence and degradability No further relevant information available.**· Behaviour in environmental systems:****· Bioaccumulative potential** No further relevant information available.**· Mobility in soil** No further relevant information available.**· Additional ecological information:****· General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· Results of PBT and vPvB assessment**· PBT:** Not applicable.**· vPvB:** Not applicable.**· Other adverse effects** No further relevant information available.

13 Disposal considerations

· Waste treatment methods**· Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to local regulations.

14 Transport information

- | | |
|---|---------------------------------------|
| · UN-Number | Not subject to transport regulations. |
| · ADR, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed
- **National regulations:**
- **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 3 Flammable liquid
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

- The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
- **Reasons for alterations** This version replaces all old versions.
 - **Relevant phrases**
H225 Highly flammable liquid and vapour.
H300 Fatal if swallowed.
H330 Fatal if inhaled.
 - **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 4: Acute toxicity – Category 4

· **Sources** GESTIS substance database

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