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

Printing date 16.03.2023 Version number 1.00 Revision: 16.03.2023

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

· **Product identifier**

· **Trade name: Opium tincture, standardised (35%)**

· **Article number:** 4904
· **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
· **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**
Flam. Liq. 3 H226 Flammable liquid and vapour.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**



GHS02

· **Signal word** Warning
· **Hazard statements**
H226 Flammable liquid and vapour.
· **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

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P103	Read carefully and follow all instructions.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
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.
· **Determination of endocrine-disrupting properties** Not applicable.

3 Composition/information on ingredients

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

· **Dangerous components:**

CAS: 64-17-5 ethanol 35.0%
EINECS: 200-578-6 Flam. Liq. 2, H225
· **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.
· **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.

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.

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· **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

· **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.
Tightly closed.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Store receptacle in a well ventilated area.
· **Storage class:** TRHS 510: 3 Flammable liquid
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:**
CAS: 64-17-5 ethanol
OEL Short-term value: 1000 ppm
· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as 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.

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· **Respiratory protection:** Respiratory protection or good ventilation of working place.
· **Hand protection** 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/face protection** Tightly sealed goggles

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Fluid
· **Colour:**	Brown
· **Odour:**	Alcohol-like
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	78 °C (CAS: 64-17-5 ethanol)
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	3.5 Vol % (CAS: 64-17-5 ethanol)
· **Upper:**	15 Vol % (CAS: 64-17-5 ethanol)
· **Flash point:**	>23 °C
· **Ignition temperature:**	425 °C (CAS: 64-17-5 ethanol)
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Fully miscible.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **Other information**
· **Appearance:**
· **Form:** Fluid

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· **Important information on protection of health and environment, and on safety.**
· **Auto-ignition temperature:** Product is not selfigniting.
· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Solvent content:**
· **Organic solvents:** 35–40 %
· **VOC (EC)** 35.00 %
· **Change in condition**
· **Evaporation rate** Not determined.

· **Information with regard to physical hazard classes**
· **Explosives** Void
Void
· **Flammable gases** Void
Void
· **Aerosols** Void
Void
· **Oxidising gases** Void
Void
· **Gases under pressure** Void
Void
· **Flammable liquids** Flammable liquid and vapour.
Void
· **Flammable solids** Void
Void
· **Self-reactive substances and mixtures** Void
Void
· **Pyrophoric liquids** Void
Void
· **Pyrophoric solids** Void
Void
· **Self-heating substances and mixtures** Void
Void
· **Substances and mixtures, which emit flammable gases in contact with water** Void
Void
· **Oxidising liquids** Void
Void
· **Oxidising solids** Void
Void
· **Organic peroxides** Void
Void
· **Corrosive to metals** Void
Void

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· **Desensitised explosives** Void
Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **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)
· **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.
· **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.
· **Information on other hazards**
· **Endocrine disrupting properties**
On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:**
CAS: 64-17-5 ethanol
LC50 14,200 mg/L (Fish)
EC50 275 mg/L (Algae)

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5,000 mg/L (invertebrates)
5,800 mg/L (Microorganism)

· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties**
Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.
The product does not contain substances with endocrine disrupting properties.
· **Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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

14 Transport information

· **UN number or ID number**
· **ADR, IMDG, IATA** UN1293
· **UN proper shipping name**
· **ADR** 1293 TINCTURES, MEDICINAL
· **IMDG** TINCTURES, MEDICINAL
· **IATA** Tinctures, medicinal
· **Transport hazard class(es)**

· **ADR, IMDG, IATA**
· **Class** 3 Flammable liquids.
· **Label** 3
· **Packing group**
· **ADR, IMDG, IATA** III
· **Environmental hazards:** Not applicable.
· **Special precautions for user** Warning: Flammable liquids.
· **Hazard identification number (Kemler code):** 30

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· **EMS Number:** F-E,S-D
· **Maritime transport in bulk according to IMO instruments** Not applicable.
· **Transport/Additional information:**

· **ADR**
· **Limited quantities (LQ)** 5L
· **Transport category** 3
· **Tunnel restriction code** D/E

· **IMDG**
· **Limited quantities (LQ)** 5L
· **UN "Model Regulation":** UN 1293 TINCTURES, MEDICINAL, 3, II

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** Conditions of restriction: 3
· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
None of the ingredients is 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.
· **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)
VOC: Volatile Organic Compounds (USA, EU)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
· **Sources** GESTIS substance database