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Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 29.10.2025 Version number 2.00 (replaces version 1.00) Revision: 29.10.2025

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

- · Product identifier
- · Trade name: Tinctura Aurantii (70%) 1:5, API
- · Article number: G258
- **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. 2 H225 Highly 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 Danger
- · Hazard statements

H225 Highly 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+P35	FON 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 63–67%

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
- · After inhalation: Fresh air. If irritation of respiratory ways continues seek medical advice.
- · 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:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

· 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 Cool endangered receptacles with water spray.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Do not inhale vapours.

Avoid contact with the substance.

- · 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 section 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.
- · 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

- · 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 section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing

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Wash hands before breaks and at the end of work.

- 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
Colour:
Odour:
Odour threshold:
Melting point/freezing point:

Liquid
Brown
Alcohol-like
Not determined.
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 Vol % (CAS: 64-17-5 ethanol) • **Upper:** 15 Vol % (CAS: 64-17-5 ethanol)

Flash point: <23 °C

• Auto-ignition temperature: 425 °C (CAS: 64-17-5 ethanol)

Decomposition temperature: Not determined.pH Not determined.

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

· Solubility

water: Fully miscible.
 Partition coefficient n-octanol/water (log value)
 Vapour pressure: Fully miscible.
 Not determined.
 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.

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: 63–69 % • VOC (EC) 63–67 %

· 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

Void

· Gases under pressure Void Void

· Flammable liquids Highly flammable liquid and vapour.

Void

· Flammable solids Void Void

· Self-reactive substances and mixtures Void Void

Pyrophoric liquids
 Pyrophoric solids
 Void
 Void
 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 solidsVoidOrganic peroxidesVoid

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)

- · 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.
- · 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)

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EC50 275 mg/L (algae)

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**

For information on endocrine disrupting properties see section 11.

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 TINCTURES, MEDICINAL Tinctures, medicinal

· Transport hazard class(es)

· ADR, IMDG, IATA

· Class 3 Flammable liquids.

· Label 3 · Packing group · ADR, IMDG, IATA II

• Environmental hazards: Not applicable.

· Special precautions for user Warning: Flammable liquids.

· Hazard identification number (Kemler code): 33 · EMS Number: F-E.S-D

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· Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· ADR

Limited quantities (LQ)
 Transport category
 Tunnel restriction code

· IMDG

· Limited quantities (LQ)

· 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.

- · Version number of previous version: 1.00
- · 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

· Sources GESTIS substance database