

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Hawthorn / Aubepine tincture
- **Article number:** 103743
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutic preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail: tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 3 H226 Flammable liquid and vapour.  
Eye Irrit. 2 H319 Causes serious eye irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** Warning
- **Hazard statements**  
H226 Flammable liquid and vapour.  
H319 Causes serious eye irritation.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

(Contd. on page 2)

CZE

**Trade name: Hawthorn / Aubepine tincture**

(Contd. of page 1)

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### **SECTION 3: Composition/information on ingredients**

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

- **Dangerous components:**

CAS: 64-17-5	ethanol	Flam. Liq. 2, H225; Eye Irrit. 2, H319	50–≤100%
EINECS: 200-578-6			

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

### **SECTION 4: First aid measures**

- **4.1 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:** Immediately rinse with water.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

(Contd. on page 3)

CZE

**Trade name: Hawthorn / Aubepine tincture**

(Contd. of page 2)

Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.

· **6.4 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.

**SECTION 7: Handling and storage**

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

· **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

**CAS: 64-17-5 ethanol**

NPK (Czechia)	Short-term value: 3000 mg/m <sup>3</sup> Long-term value: 1000 mg/m <sup>3</sup>
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- **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Fresh air mask
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has

(Contd. on page 4)

CZE

Trade name: Hawthorn / Aubepine tincture

(Contd. of page 3)

therefore to be checked prior to the application.

· **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

· **Body protection:** Protective work clothing

**SECTION 9: Physical and chemical properties**

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

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Brown

· **Odour:**

Characteristic

· **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**

Flammable.

· **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 at 20°C:**

1,000 g/l

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure at 20°C:**

59 hPa (CAS: 64-17-5 ethanol)

· **Density and/or relative density**

· **Density at 20°C:**

0,91–0,94 g/cm<sup>3</sup>

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **9.2 Other information**

· **Appearance:**

· **Form:**

Fluid

· **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:**

53–58 %

(Contd. on page 5)

CZE

Trade name: Hawthorn / Aubepine tincture

(Contd. of page 4)

· VOC (EC)	53–58 %
· Solids content:	0,0 %
· Molecular weight	46 g/mol
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

- **11.1 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	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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.

(Contd. on page 6)

CZE

Trade name: Hawthorn / Aubepine tincture

(Contd. of page 5)

- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely 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.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
  - **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
  - **European waste catalogue**
- |     |   |
|-----|---|
| HP3 | Flammable                                 |
| HP4 | Irritant - skin irritation and eye damage |
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

- |                                       |                      |
|---------------------------------------|----------------------|
| · <b>14.1 UN number or ID number</b>  |                      |
| · <b>ADR, IMDG, IATA</b>              | UN1293               |
| · <b>14.2 UN proper shipping name</b> |                      |
| · <b>ADR, IMDG</b>                    | TINCTURES, MEDICINAL |
| · <b>IATA</b>                         | Tinctures, medicinal |

(Contd. on page 7)

CZE

Trade name: Hawthorn / Aubepine tincture

(Contd. of page 6)

· 14.3 Transport hazard class(es)

· ADR, IMDG, IATA



· Class 3 Flammable liquids.  
· Label 3

· 14.4 Packing group

· ADR, IMDG, IATA II

· 14.5 Environmental hazards: Not applicable.

· 14.6 Special precautions for user Warning: Flammable liquids.

· Hazard identification number (Kemler code): 33

· EmS Number: F-E,S-D

· Stowage Category B

· 14.7 Maritime transport in bulk according to IMO instruments Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ) 1L

· Excepted quantities (EQ) Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

· Transport category 2

· Tunnel restriction code D/E

· IMDG

· Limited quantities (LQ) 1L

· Excepted quantities (EQ) Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation": UN 1293 TINCTURES, MEDICINAL, 3, II

**SECTION 15: Regulatory information**

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category P5c FLAMMABLE LIQUIDS

· Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t

· Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

(Contd. on page 8)

CZE



**Trade name: Hawthorn / Aubepine tincture**

(Contd. of page 7)

· **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.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

· **Department issuing SDS:** Fagron Česká republika

· **Contact:** msds@fagron.cz

· **Date of previous version:** 13.12.2022

· **Version number of previous version:** 1.1

· **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)

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

· **\* Data compared to the previous version altered.**

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