Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CRATAEGI TINCTURA

Publication: 21/03/2022
Revision: 21/03/2022
Version: 00

MAGIS PHARMA

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Hawthorn tincture
	Crataegi tinctura
	Meidoorntinctuur
	Teinture d'aubépine
	Weißdorn Tinktur
N° CAS:	N/A
N° EC:	N/A

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	FRAVER NV
	Keizershoek 336
	2550 Kontich
	Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Flam. Liq. 3	H226
Eye Irrit. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):
Attention
Flammable
Irritant

Hazard statements:

H226	Flammable liquid and vapour.
H319	Causes serious eye irritation.

Precautionary statements:

P210	Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Ethanolic preparation of Crataegus monogyna Jacq. (Lindm.)/Crataegus laevigata (Poiret) D.C.

Product name:	Ethanol
IUPAC name:	Ethanol
Synonyms:	Ethyl alcohol
	Alcohol
N° CAS:	64-17-5
N° EC:	200-578-6
Molecular Formula:	C_2H_6O
Content:	35 – 45 % *V/V* %

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Fresh air. Consult doctor if feeling unwell.
After skin contact	Wash off with plenty of water.
After eye contact:	Rinse out with plenty of water with the eyelid held wide open. Consult eye doctor.
After ingestion:	If victim is still conscious, make him drink plenty of water, Consult doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects, euphoria, dizziness, inebriation, narcosis, respiratory paralysis.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	CO_2, water, foam, powder.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Combustible material, Development of hazardous combustion gases and vapours possible in the event of fire.

5.3 Advice for firefighters

Surrounding fires:	Remove container from danger zone and cool with water.
Protection against fire:	In the event of fire, wear self-contained breathing apparatus.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Do not breathe vapours/aerosols. Wear protective clothing.

For emergency responders

Do not breathe vapours/aerosols. Wear protective clothing.

6.2 Environmental precautions

Do not empty into drains. Risk of explosion.

6.3 Methods and material for containment and cleaning up

Take up with liquid-absorbent material. Forward for disposal. Clean up affected area.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Observe label precautions.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In tightly closed containers.
Conditions for safe storage, including any incompatibilities:	Tightly closed at a cool dark and dry place. (15 – 20 °C) Containers in plastic should be avoided.
Storage – away from:	Store protected from light. Keep container away from sources of ignition.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ethanol	Germany (TRGS 900)	500 mL/m^3	960 mg/m^3
	USA (NIOSH)	1000 mL/m^3	1900 mg/m^3
	USA (OSHA)	1000 mL/m^3	1900 mg/m^3

Derived No Effect Level (DNEL)

Ethanol

Worker DNEL, acute	Local effects	inhalation	1900 mg/m^3
Worker DNEL, long-term	Systemic effects	dermal	343 mg/kg Body weight
Worker DNEL, long-term	Systemic effects	inhalation	950 mg/m^3
Consumer DNEL, acute	Local effects	inhalation	950 mg/m^3
Consumer DNEL, long-term	Systemic effects	dermal	206 mg/kg Body weight
Consumer DNEL, long-term	Systemic effects	inhalation	114 mg/m^3
Consumer DNEL, long-term	Systemic effects	oral	87 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

Ethanol

PNEC Fresh water	0.96 mg/L
PNEC Marine water	0.79 mg/L
PNEC Fresh water sediment	3.6 mg/kg
PNEC Soil	0.63 mg/kg
PNEC Aquatic intermittent release	2.75 mg/L
PNEC Sewage treatment plant	580 mg/L
PNEC oral	720 mg/kg

8.2 Exposure controls

Appropriate engineering control

Industrial hygiene: Change contaminated clothing. Wash hands and face after working with substance. Under no circumstances eat or drink at workplace.

Individual protection measures

Eye/face protection: Required (EN 166).

Skin protection: Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Hand protection:

In full contact:	Glove material:	Butyl rubber
	Layer thickness:	0.7 mm
	Breakthrough time:	> 480 min
In splash contact:	Glove material:	Nitrile rubber
	Layer thickness:	0.4 mm
	Breakthrough time:	> 120 min

The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN 374 for example KCL 898 Butoject.

Additional reference: The data are based on own examinations, literature data and information from glove manufacturers or are derived by analogy reasoning from similar materials. It is to be noted that the daily life of a chemical protection glove can be clearly shorter in practice because of the many factors of influence (e.g. temperature, stretch etc.) than the permeation time determined after EN 374.

Respiratory protection: Required when dusts are generated, Filter A-(P2) (EN 141).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Brown liquid.
Odour:	Aromatic, characteristic.
Odour threshold:	Not available.
pH:	About 5.5
Melting/freezing point:	Not available.
Initial boiling point:	84 °C
Boiling range:	Not available.

Flash point:	27.0 °C (DIN 51 755 Abel-Pensky)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	Completely miscible.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Density (20 °C): 0.900 – 1.000

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Vapours may form explosive mixture with air.

10.2 Chemical stability

Stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Risk of ignition or formation of inflammable gases or vapours with: Alkali metals, alkali oxides, anhydrides, strong oxidizing agents.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Various plastics, rubber.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Ethanol		
	LD_{50}	oral rat	6200 mg/kg
	LD_{50}	dermal rabbit	> 20000 mg/kg
	LC_{50}	inhalation rat	> 8000 mg/L/ 4h
Skin corrosion/irritation:	Not available.		
Serious eye damage/irritation:	Not available.		

Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Systemic effects: euphoria. After absorption of large quantities: dizziness, inebriation, narcosis, respiratory paralysis The product should be handled with the care usual when dealing with chemicals

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	After eye contact: slight irritations. Causes serious eye irritation.
Skin contact:	Not available.
Inhalation:	After inhalation of vapours: slight mucosal irritations. Risk of absorption.
Ingestion:	After swallowing of large amounts: nausea and vomiting.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

For this product no quantitative data available.

12.2 Persistence and degradability

Biodegradability Ethanol 94% OECD 301E

12.3 Bioaccumulative potential

Bioaccumulation is not expected (log P (o/w) < 1).

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT-/vPvB assessment not available as chemical safety assessment not required.

12.6 Other adverse effects

No ecological problems are to be expected when the product is handled and used with due care and attention

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Contact a licensed professional waste disposal service to dispose of this material.

Observe all federal, state and local environmental regulations

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	1169

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	EXTRACTS AROMATIC LIQUID

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	3

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR/RID: Environmentally hazardous: No. IATA: Environmentally hazardous: No.

14.6 Special precautions for user

ADR/RID	Classification: F1
IMDG	EmS: F-E S-D

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

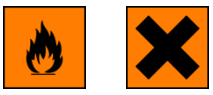
The transport regulations are cited according to international regulations and in form applicable in Germany.

Possible national deviations in other countries are not considered.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Flammable
Irritant

Risk phrases: R10 Flammable.
R36 Irritating to eyes.

Safety phrases: S16 Keep away from sources of ignition – No smoking.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)

IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Classification based on the main component.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FRAVER NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FRAVER NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FRAVER NV

info@magis-pharma.be