

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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## PASSIFLORAE HERBAE TINCTURA

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

#### 1.1 Product identifier

Product name:	Passion flower tincture Passiflorae herbae tinctura Passiebloemtinctuur Teinture de passiflore Passionsblume 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.
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#### 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  
Warning

Hazard statements:  
H226  
Flammable liquid and vapour.

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H319 Causes serious eye irritation.

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces and other ignition sources—  
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

Ethanol preparation of *Passiflora incarnata* L. (Passionflowers)

Product name: Ethanol

IUPAC name: Ethanol

Synonyms: Ethyl alcohol

Methylcarbinol

N° CAS: 64-17-5

N° EC: 200-578-6

Molecular Formula: C<sub>2</sub>H<sub>6</sub>O

## 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<sub>2</sub>, water, foam, powder.

Unsuitable extinguishing media: Not available.

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### 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:	Not available.
Conditions for safe storage, including any incompatibilities:	Tightly closed at a cool dark and dry place (15 - 20 °C).
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

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Ethanol	Germany (TRGS 900)	500 ml/m <sup>3</sup>	960 mg/m <sup>3</sup>
	USA (NIOSH)	1000 ml/m <sup>3</sup>	1900 mg/m <sup>3</sup>
	USA (OSHA)	1000 ml/m <sup>3</sup>	1900 mg/m <sup>3</sup>

### Derived No Effect Level (DNEL)

#### Ethanol

Worker DNEL, acute	Local effects	Inhalation	1900 mg/m <sup>3</sup>
Worker DNEL, long-term	Systemic effects	Dermal	343 mg/kg Body weight
Worker DNEL, long-term	Systemic effects	Inhalation	950 mg/m <sup>3</sup>
Consumer DNEL, acute	Local effects	Inhalation	950 mg/m <sup>3</sup>
Consumer DNEL, long-term	Systemic effects	Dermal	206 mg/kg Body weight
Consumer DNEL, long-term	Systemic effects	Inhalation	114 mg/m <sup>3</sup>
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 the 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 derived standard EN 374, for example KCL 898 Butoject.

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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:	Greenish-brown liquid.
Odour:	Spicy.
Odour threshold:	Not available.
pH:	5 – 7
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: 0.930 – 0.990 (20 °C)

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### 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 <sub>50</sub>	oral rat	6200 mg/kg
	LD <sub>50</sub>	dermal rabbit	> 20000 mg/kg
	LC <sub>50</sub>	inhalation rat	> 8000 mg/L/4h
Skin corrosion/irritation:	Not available.		
Serious eye damage/irritation:	Slight irritations.		
Respiratory/skin sensitisation:	After inhalation of vapours: slight mucosal irritations. Risk of absorption		
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: Causes serious eye irritation.

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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

Not 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) : 1197

##### 14.2 UN proper shipping name

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

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : 3  
ADR/RID: F1

##### 14.4 Packing group

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

### 14.5 Environmental hazards

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

### 14.6 Special precautions for user

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:



Highly 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



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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 Bioaccumulative

### 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.

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### 16.8 Department issuing MSDS

Quality Department

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