

# 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 EXTRACTUM SICCUM

Publication: 26/04/2022

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Version: 00



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

#### 1.1 Product identifier

Product name:	Passion flower dry extract Passiflorae herbae extractum siccum Passiebloem droog extract Passiflore (extrait sec de) Passionsblume Trockenextrakt
N° CAS:	72968-47-9
N° EC:	277-142-7

#### 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:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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

Classification: Non-hazardous substance.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

#### 2.3 Other hazards

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None.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Passion flower dry extract
IUPAC name:	Passiflora incarnata extract
Synonyms:	Passionflower Passiflora incarnata extract
N° CAS:	72968-47-9
N° EC:	277-142-7
Molecular Formula:	Not available.
Content:	Minimum 2.0 per cent of flavonoids, expressed as vitexin (C <sub>21</sub> H <sub>20</sub> O <sub>10</sub> ; Mr 432.4) (dried extract). Production: The extract is produced from the herbal drug ( <i>Passiflora incarnata</i> L.) and ethanol (70 per cent V/V) by an appropriate procedure. Excipients: Maltodextrinum (58%) + Silica colloidalis anhydrica (2%) Extraction solvent: Ethanol (70% V/V)

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	In case of accident, consult a doctor.
After inhalation:	Breathe in fresh air.
After skin contact:	Wash with soap and water.
After eye contact:	Rinse with plenty of water.
After ingestion:	Drink plenty of water.

#### 4.2 Most important symptoms and effects, both acute and delayed

None.

#### 4.3 Indication of any immediate medical attention and special treatment needed

None.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Water, foam, carbon dioxide, dry chemicals.
Unsuitable extinguishing media:	Not known.

#### 5.2 Special hazards arising from the substance/mixture

Not known.

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### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	It is recommended to wear oxygen masks.
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 dust, avoid contact with skin and mucous membranes and use personal protective equipment as described (section 8).

#### For emergency responders

Do not breathe dust, avoid contact with skin and mucous membranes and use personal protective equipment as described (section 8).

### 6.2 Environmental precautions

Do not discharge the product into the sewage system or directly into the environment.

### 6.3 Methods and material for containment and cleaning up

Sweep up spilled material, avoiding dust.  
Store in a container.  
Small amounts can be washed with soap and water.

### 6.4 Reference to other sections

See section 8.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin, eyes and mucous membranes, and avoid breathing dust. Try to avoid generating dust.
Personal protection:	Not available.
Technical protective measures:	Try to avoid generating dust.
Handling:	Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Store tightly at room temperature protected from light and moisture.
Storage – away from:	Store protected from light and moisture. Storage with foodstuffs and chemicals is not recommended.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Not available.

#### 8.2 Exposure controls

##### Appropriate engineering control

Not available.

##### Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Appropriate clothing.

Hand protection: Gloves.

Respiratory protection: Dust mask.

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 amorphous powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

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: Soluble in hydroalcoholic solutions.

Solubility in water: Not available.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

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Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

### 9.2 Other information

None.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Acids, bases, corrosives and oxidising substances.

### 10.6 Hazardous decomposition products

Combustion may generate CO, CO<sub>2</sub> as well as unidentified organic and inorganic compounds.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Not available.

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: Not available.

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### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	If the product is used properly, it should not cause relevant problems.
Skin contact:	If the product is used properly, it should not cause relevant problems.
Inhalation:	If the product is used properly, it should not cause relevant problems.
Ingestion:	If the product is used properly, it should not cause relevant problems.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not required.

### 12.6 Other adverse effects

No environmental problems can occur if the product is handled and used with care.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: It is the responsibility of the user to comply with local and national laws, regulations, legislation and standards. Packaging: Containers should be treated in the same way as the product. Clean containers should be treated as household waste or recycling.

## 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) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.3 Transport hazard class(es)

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ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not available.

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

Not available.

### 14.8 Additional transport information

Non-hazardous substance.

No labelling is required in accordance with the Transport of Dangerous Goods Regulations.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable

Risk phrases: Not applicable

Safety phrases: Not applicable.

### 15.2 Chemical safety assessment

Not required.

## 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

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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

Not applicable.

### 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

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