

Material Safety Data Sheet

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

EN

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Revision: XX/XX/XXXX

Version: 00



VALERIANAE EXTRACTUM HYDROALCOHOLICUM SICCUM

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

1.1 Product identifier

Product name:	Valerian dry hydroalcoholic extract Valerianae extractum hydroalcoholicum siccum Valeriaan droog hydroalcoholisch extract Valériane (extrait hydroalcoolique sec de) Hydroalkoholischer Trockenextrakt aus Baldrian
N° CAS:	8057-49-6
N° EC:	232-501-7

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

According to Regulation (EC) No. 286/2011 amending regulation (EC) No. 1272/2008: Not 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

Extract produced from *Valerian root*.

Product name: Valerian dry hydroalcoholic extract

IUPAC name: Not available.

Synonyms: Valerian root extract
Valerian, extr.

N° CAS: 8057-49-6

N° EC: 232-501-7

Molecular Formula: Not available.

Content: Minimum 0.25 per cent *m/m* of sesquiterpenic acids, expressed as valerenic acid (C₁₅H₂₂O₂; M_r 234.3) (substance as is).

The extract is produced from the herbal drug by a suitable procedure using ethanol (30-90 per cent V/V) or methanol (40-55 per cent 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 physician.

After inhalation: Breathe in fresh air.

After skin contact: Wash with soap and water.

After eye contact: Flush thoroughly with 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 chemical products.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance/mixture

Not known.

5.3 Advice for firefighters

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Surrounding fires:	Not available.
Protection against fire:	Entering in any enclosed or confined fire space without self-contained breathing apparatus is not recommended
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, eyes and mucous membranes and use the personal protective equipment according to section 8.

For emergency responders

Do not breathe dust, avoid contact with skin, eyes and mucous membranes and use the personal protective equipment according to section 8.

6.2 Environmental precautions

Avoid disposing into sewer system or directly into environment.

6.3 Methods and material for containment and cleaning up

Sweep up spilled product avoiding dust. Collect in a container. Small quantities 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 any contact with skin, eyes and mucous membranes. Try to avoid dust generation.
Personal protection:	Not available.
Technical protective measures:	Try to avoid dust generation.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	The product does not require any special storage conditions. The storage with foodstuff and chemical products is not recommended.
Storage – away from:	Store protected from light. The storage with foodstuff and chemical products is not recommended.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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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:	Wear suitable clothes.
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:	Brown, hygroscopic 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:	Partially soluble in hydroalcoholic solutions.
Solubility in water:	Partially soluble in water.
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

Acid, base corrosive and oxidizing substances.

10.6 Hazardous decomposition products

Burning may generate CO, CO₂ and 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.

11.2 Additional information on potential adverse human health effects and symptoms

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Eye contact:	This product should present no significant problems to typical persons in normal use.
Skin contact:	This product should present no significant problems to typical persons in normal use.
Inhalation:	This product should present no significant problems to typical persons in normal use.
Ingestion:	This product should present no significant problems to typical persons in normal use.
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 applicable

12.6 Other adverse effects

None. No ecological problems are to be expected when the product is handled and used with care and attention.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: It is the user's responsibility to comply with all local and national laws, rules, regulations and standards.

Packaging: Material with remaining product should be treated as the product. The clean containers will be treated as domestic waste or recycling material.

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

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

14.3 Transport hazard class(es)

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

It is not classified as dangerous product. It is not necessary to label according to the dangerous products 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

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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 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

Quality Department

FAC SECUNDUM ARTEM NV

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