

# 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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## BELLADONNAE FOLII EXTRACTUM SICCCUM NORMATUM

Publication: 02/02/2022

Revision: 02/02/2022

Version: 00



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

#### 1.1 Product identifier

Product name:	Belladonna leaf dry extract, standardised Belladonnae folii extractum siccum normatum Belladonna blad droog extract, gestandaardiseerd Belladone (feuille de), extrait sec titré de Belladonna Blatt Trockenextrakt, standardisiert
N° CAS:	Not available.
N° EC:	Not available.

#### 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

Acute Tox. 2	H300
Acute Tox. 4	H302
Acute Tox. 2	H330
Acute Tox. 4	H332

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H300	Fatal if swallowed.
H302	Harmful if swallowed.

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H330	Fatal if inhaled.
H332	Harmful if inhaled.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P301	IF SWALLOWED:
P312	Call a doctor if you feel unwell.
Additional applicable label elements:	

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Belladonna leaf dry extract, standardised
IUPAC name:	Not available.
Synonyms:	Atropa belladonna Belladonna, ext.
N° CAS:	Not available.
N° EC:	Not available.
Molecular Formula:	Not available.
Content:	0.95 per cent to 1.05 per cent of total alkaloids, expressed as hyoscyamine (C <sub>17</sub> H <sub>23</sub> NO <sub>3</sub> ) (dried extract). The extract is produced from the herbal drug by suitable procedure using ethanol (70 per cent V/V). Excipients: Lactose monohydrate (CAS: 10039-26-6; EC: 200-559-2), Colloidal anhydrous silica (CAS: 7631-86-9; EC: 231-545-4).

### 3.2 Mixtures

Not applicable.

## 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

Not available.

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

Not available.

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### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: CO<sub>2</sub>, water, foam, powder.

Unsuitable extinguishing media: Not available.

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

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

#### 5.3 Advice for firefighters

Surrounding fires: Not available.

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

Avoid generation of dusts, do not inhale dusts. Wear protective clothing.

##### For emergency responders

Avoid generation of dusts, do not inhale dusts. Wear protective clothing.

#### 6.2 Environmental precautions

Do not empty into drains.

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

Take up dry.

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 away from light.

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### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Siliciumdioxid, Germany (TRGS 900): 0.3 mg/m<sup>3</sup> (respirable fraction)

Derived No Effect Level (DNEL), siliciumdioxid:

Worker DNEL, acute	Local effects	inhalation	0.3 mg/m <sup>3</sup>
Worker DNEL, long term	Systemic effects	inhalation	0.05 mg/m <sup>3</sup>

### 8.2 Exposure controls

#### Appropriate engineering control

Industrial hygiene: Change contaminated clothing. Wash hands and face after working with substance. Do not eat or drink in 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 resultant standard EN 374, for example KCL 898 Butoject.

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 or greenish, hygroscopic powder.
Odour:	Aromatic, herb
Odour threshold:	Not available.
pH:	About 4.5 (10% H <sub>2</sub> O-suspension)

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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:	Not available.
Solubility in water:	Not available.
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

Bulk density: 50.0 – 80.0 g/100ml (20°C) (Ph. Eur. 2017)

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Dusts may form explosive mixture with air.

### 10.2 Chemical stability

Stable under standard ambient conditions (room temperature).

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Strong heating.

### 10.5 Incompatible materials

Not available.

### 10.6 Hazardous decomposition products

Not available.

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Slight irritations.
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:	The product should be handled with the usual care when dealing with chemicals.

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

Eye contact:	Slight irritations.
Skin contact:	Not available.
Inhalation:	After inhalation of dusts: Face redness, dry mucosa.
Ingestion:	Not available.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Not available.

#### 12.3 Bioaccumulative potential

Bioaccumulation is not expected.

#### 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.

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### 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) : Not classified.

##### 14.2 UN proper shipping name

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

Not a subject to transport regulations. 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

N/A

#### 15.2 Chemical safety assessment

Not available.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

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### 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 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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