

Trade name: Betulae fol extr aqu sicc

Substance number: 121285

Version: 1 / CH

Date revised: 27.02.2024

Replaces Version: - / CH

Print date: 27.02.24

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Betulae fol extr aqu sicc

Item No. 12128500

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Active pharmaceutical substance

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

Supplemental information

EUH210 Safety data sheet available on request.

2.3. Other hazards

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients

Chemical characterization

Extract of herbal drugs

Hazardous ingredients

2-(3,4-dihydroxyphenyl)-3-(β-D-galactopyranosyloxy)-5,7-dihydroxy-4H-1-benzopyran-4-one

CAS No. 482-36-0

EINECS no. 207-580-6

Concentration >= 1 < 10 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4

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cATpE oral 500 mg/kg

Further ingredients

Maltodextrin
 CAS No. 9050-36-6
 EINECS no. 232-940-4
 Concentration \geq 1 < 10 %
 Advice: [4]

Silicon dioxide, chemically prepared, amorphous
 CAS No. 7631-86-9
 EINECS no. 231-545-4
 Registration no. 01-2119379499-16-0000 (TPR)
 Concentration < 1 %
 Advice: [4]

Name of set of nanoform	Nanoaggregate	
	>100	nm
Shape and aspect ratio of particles	Spheroidal	
	Nanoaggregate	
	>100	nm
Shape and aspect ratio of particles	amorphous	
Particle size distribution	Nano particles	
	d50 2.5-50	nm
	Method	Transmission Electron Microscopy (TEM)

Note

[4] Voluntary information

Other information

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

In case of persistent symptoms consult doctor.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Rinse out mouth and give plenty of water to drink.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

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

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Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Foam, Carbon dioxide, Dry powder, Water spray jet

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

In case of combustion use a suitable breathing apparatus.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid dust formation.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Clean contaminated floors and objects thoroughly, observing environmental regulations.

6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Observe the usual precautions for handling chemicals.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed and dry.

Hints on storage assembly

Do not store together with foodstuffs.

Storage classes

Storage class according to TRGS 510

11

Combustible solids

Storage category (Switzerland)

11/13

Other solid hazardous substances with classification/labelling hazardous

Further information on storage conditions

Keep container tightly closed and dry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

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Other information

Contains no substances with occupational exposure limit values.

8.2. Exposure controls**General protective and hygiene measures**

Observe the usual precautions for handling chemicals.

Respiratory protection

If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn.

Dust mask

Hand protection

In case of intensive contact wear protective gloves.

Appropriate Material neoprene

Eye protection

Safety glasses

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	solid		
Colour	light brown		
Physical state	Powder		
Melting point			
Remarks	not determined		
Freezing point			
Remarks	not determined		
Boiling point or initial boiling point and boiling range			
Remarks	not determined		
Flammability	not determined		
Upper and lower explosive limits			
Remarks	not determined		
Flash point			
Value	> 80		°C
Ignition temperature			
Remarks	not determined		
Decomposition temperature			
Remarks	not determined		
pH value			
Remarks	not determined		
Viscosity			
Remarks	not determined		
Solubility(ies)			
Remarks	not determined		
Partition coefficient n-octanol/water (log value)			
Remarks	not determined		

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Vapour pressure

Remarks Not applicable

Density and/or relative density

Remarks not determined

Relative vapour density

Remarks not determined

9.2. Other information**Odour threshold**

Remarks not determined

Evaporation rate (ether = 1) :

Remarks not determined

Solubility in water

Remarks soluble

Bulk density

Value 0.4 to 0.8 g/ml

SECTION 10: Stability and reactivity**10.1. Reactivity**

Accumulation of fine dust may entail the risk of a dust explosion in the presence of air.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No decomposition if stored and applied as directed.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

ATE	>	10'000	mg/kg
Method		calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species	rat		
LD50		3160	mg/kg

Silicon dioxide, chemically prepared, amorphous

Species	rat		
LD50	>	5000	mg/kg
Method		OECD 401	

Silicon dioxide, chemically prepared, amorphous

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NOAEL >= 1000 mg/kg
Duration of exposure 28 d

Acute dermal toxicity

Remarks not determined

Acute dermal toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species rabbit
LD50 > 5000 mg/kg

Acute inhalational toxicity

Remarks not determined

Acute inhalative toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species rat
LC50 > 5.01 mg/l
Duration of exposure 4 h
Administration/Form Dust/Mist

Skin corrosion/irritation

Remarks not determined

Skin corrosion/irritation (Components)**Silicon dioxide, chemically prepared, amorphous**

Species rabbit
evaluation non-irritant

Serious eye damage/irritation

Remarks not determined

Serious eye damage/irritation (Components)**Silicon dioxide, chemically prepared, amorphous**

evaluation non-irritant

Sensitization

Remarks not determined

Subacute, subchronic, chronic toxicity

Remarks not determined

Mutagenicity

Remarks not determined

Mutagenicity (Components)**Silicon dioxide, chemically prepared, amorphous**

evaluation Based on available data, the classification criteria are not met.
Method OECD 471

Silicon dioxide, chemically prepared, amorphous

Method OECD 473

Silicon dioxide, chemically prepared, amorphous

evaluation Not considered mutagenic based on several in vitro and in vivo studies.

Reproductive toxicity

Remarks not determined

Reproduction toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

evaluation Based on available data, the classification criteria are not met.

Carcinogenicity

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Remarks not determined

Carcinogenicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Remarks No evidence available on carcinogenicity.

11.2 Information on other hazards**Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

Other information

No toxicological data are available.

SECTION 12: Ecological information**12.1. Toxicity****General information**

not determined

Fish toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species	zebra fish (<i>Brachydanio rerio</i>)		
LC50	>	10000	mg/l
Duration of exposure	96	h	
Remarks	The details of the toxic effect relate to the nominal concentration.		

Daphnia toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species	Daphnia magna		
EC50	>	1000	mg/l
Duration of exposure	24	h	
Remarks	The details of the toxic effect relate to the nominal concentration.		

Algae toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species	Desmodesmus subspicatus		
EC50	>	173	mg/l
Duration of exposure	72	h	
Method	OECD 201		

Bacteria toxicity (Components)**Silicon dioxide, chemically prepared, amorphous**

Species	activated sludge		
EC50	>	2500	mg/l
Duration of exposure	3	h	
Method	OECD 209		

12.2. Persistence and degradability**General information**

not determined

Biodegradability (Components)**Silicon dioxide, chemically prepared, amorphous**

Remarks Inorganic product, cannot be eliminated from the water by biological purification processes.

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12.3. Bioaccumulative potential**General information**

not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

12.4. Mobility in soil**General information**

not determined

Mobility in soil (Components)

Silicon dioxide, chemically prepared, amorphous
Immobile

12.5. Results of PBT and vPvB assessment**Results of PBT and vPvB assessment**

The product contains no PBT substances
The product contains no vPvB substances.

12.6 Endocrine disrupting properties**Endocrine disrupting properties with respect to the environment**

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects**General information**

not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

Disposal in compliance with local and national regulations.
Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off as product waste.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information

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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**Water Hazard Class (Germany)**

Water Hazard Class (Germany) WGK 2

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.