

Trade name: Belladonnae extr sicc norm

Substance number: 121200

Version: 4 / CH

Date revised: 09.11.2020

Replaces Version: 3 / CH

Print date: 09.11.20

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

1.1. Product identifier

Belladonnae extr sicc norm

Item No. 12120000

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

Use of the substance/preparation

Active pharmaceutical substance, Manufacture of pharmaceutical products

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

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

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

Acute Tox. 4 H302

Acute Tox. 4 H332

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

H332 Harmful if inhaled.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264.1 Wash hands thoroughly after handling.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position

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P312 comfortable for breathing.
 Call a POISON CENTRE or doctor if you feel unwell.
 P330 Rinse mouth.
 P501.3 Disposal in compliance with local and national regulations.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains hyoscyamine

SECTION 3: Composition/information on ingredients *****3.2. Mixtures****Chemical characterization**

Extract of herbal drugs

Hazardous ingredients**hyoscyamine**

CAS No.	101-31-5			
EINECS no.	202-933-0			
Concentration	>= 1	<	1.6	%
Classification (Regulation (EC) No. 1272/2008)	Acute Tox. 2		H300	
	Acute Tox. 2		H330	

Further ingredients *****Lactose**

CAS No.	63-42-3			
EINECS no.	200-559-2			
Concentration		>=	50	%
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		>=	50	%
Advice: [4]				

Note

[4] Voluntary information

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Ensure supply of fresh air. Summon a doctor immediately.

After skin contact

After contact with skin, wash immediately with plenty of water. Remove contaminated, soaked clothing immediately and dispose of safely.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Summon a doctor immediately.

After ingestion

Let plenty of water be drunk in small gulps. Summon a doctor immediately.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Extinguishing measures to suit surroundings, Water spray jet, Foam, Dry powder, Carbon dioxide

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

If a fire breaks out nearby evolution of dangerous gases possible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not inhale dust. Wear protective equipment

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

To pick up dry. Avoid raising dust. Dampen, pick up mechanically and dispose of. Rinse away rest with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe safety references and application instructions mentioned on can. Avoid the formation and deposition of dust. Use only in well-ventilated areas. Smoking, eating and drinking should be prohibited in application area. Do not allow to enter drains or water courses.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value	15	20	°C
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Storage classes

Storage class according to TRGS 510	6.1D	Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects
Storage category (Switzerland)	11/13	Other solid hazardous substances with classification/labelling hazardous

Further information on storage conditions

Protect from light. Keep containers tightly closed in a dry, cool and well-ventilated place.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

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Silicon dioxide, chemically prepared, amorphous

List	SUVA
Type	MAK
Value	4 mg/m ³
Pregnancy group: S; Remarks: SSc; LungenfibKT AN	

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

Do not eat or drink during work time. Clean skin thoroughly after work; apply skin cream.

Respiratory protection

Provide good ventilation of working area (local exhaust ventilation if necessary). In case of insufficient ventilation, wear suitable respiratory equipment. Particle filter half mask, filter FFP2 - Norm DIN EN 149

Hand protection

Use	Permanent hand contact
Appropriate Material	Butyl rubber - Butyl
Material thickness	0.7 mm
Breakthrough time	> 480 min
Use	Short-term hand contact
Appropriate Material	nitrile rubber - NBR
Material thickness	0.4 mm
Breakthrough time	> 120 min

Eye protection

Tightly fitting safety glasses

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

Form	Powder
Colour	grey to black
Odour	aromatic
pH value	
Value	4.4
Concentration/H ₂ O	10 %
Temperature	20 °C
Flash point	
Value	°C
Remarks	Not applicable
Vapour pressure	
Remarks	not determined
Density	
Value	659 g/l
Solubility(ies)	
Remarks	Difficult to dissolve

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. No decomposition if stored and applied as directed.

10.2. Chemical stability

No decomposition if stored and applied as directed.

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10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No hazardous decomposition products known when handled according to prescribed instructions.

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

ATE	400	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

Acute inhalational toxicity

ATE	4	mg/l
Administration/Form	Dust/Mist	
Method	calculated value (Regulation (EC) No. 1272/2008)	

Serious eye damage/irritation

Remarks	Irritates the eyes.
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Other information

Observe the usual precautions for handling chemicals.

SECTION 12: Ecological information**12.1. Toxicity****Fish toxicity**

Remarks	Quantitative data concerning the ecological effect are not available.
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12.2. Persistence and degradability**General information**

No data available

12.3. Bioaccumulative potential**General information**

There is no data available on the product apart from the information given in this subsection.

12.4. Mobility in soil**General information**

No data available

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

No data available

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12.6. Other adverse effects**General information**

Not relevant

General information / ecology

Ecological data are not available.

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

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

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

Water Hazard Class (Germany) WGK 3

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**

H300 Fatal if swallowed.

H330 Fatal if inhaled.

CLP categories listed in Chapter 3

Acute Tox. 2 Acute toxicity, Category 2

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.