

Safety data sheet according to 1907/2006/EC, Article 31

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Printing date 30.05.2018 Revision: 30.05.2018 Version number 3

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

· 1.1 Product identifier

· Trade name: digitonin

· Article number: A1905

· CAS Number:

11024-24-1 • **EC number:** 234-255-6

· Registration number

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not requiere a registration, the registration is envisaged for a later registration deadline or it is a mixture.

- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture

Pharmaceutical analysis Laboratory chemical

- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

AppliChem GmbH Ottoweg 4 D-64291 Darmstadt Tel.: +49 (0)6151 93570 Fax.: +49 (0)6151 935711 msds@applichem.com

- · Further information obtainable from: Dept. Compliance
- 1.4 Emergency telephone number: +49(0)6151 93570 (Inside normal buisness hours)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.

Acute Tox. 3 H331 Toxic if inhaled.

- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS06

- · Signal word Danger
- · Hazard statements

H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

· Precautionary statements

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

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P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P361+P364 Take off immediately all contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT: Not applicable.vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Chemical characterisation: Substances

· CAS No. Description

11024-24-1 digitonin

· Identification number(s)

· EC number: 234-255-6

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

Involve doctor immediately.

· After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.

· After skin contact:

Call a doctor immediately.

Immediately wash with water and soap and rinse thoroughly.

Immediately remove any clothing soiled by the product.

· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing:

Do not induce vomiting; call for medical help immediately.

Call a doctor immediately.

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

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

In adaption to materials stored in the immediate neighbourhood.

• 5.2 Special hazards arising from the substance or mixture

carbon oxides (CO, CO2).

Non-combustible.

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· 5.3 Advice for firefighters

· Protective equipment:

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

· Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Do not inhale dust.

Avoid substance contact.

Ensure adequate ventilation

- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Avoid generation of dusts.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Clean up affected area.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Any unavoidable deposit of dust must be regularly removed.

· Information about fire - and explosion protection:

Keep respiratory protective device available.

The product is not flammable.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Store receptacle in a well ventilated area.

Store under lock and key and with access restricted to technical experts or their assistants only.

- · Recommended storage temperature: +15 +25°C
- · Storage class: 6.1 D
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.

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- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Vacuum clean contaminated clothing. Do not blow or brush off contamination.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Filter P3

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact gloves made of the following materials are suitable:

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

Value for the permeation: Level ≥ 480 min

· As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

Value for the permeation: Level ≥ 480 min

- · Eye protection: Safety glasses
- · Body protection:

Use protective suit.

Full head, face and neck protection

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazourdous substances handled.

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Solid
Colour: White

Odour: Odourless

Odour threshold: Not determined.

· **pH-value:** Not applicable.

· Change in condition

Melting point/freezing point: 235-240 °C

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Initial boiling point and boiling range: Undetermined.		
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Product is not flammable.	
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Not determined.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapour pressure:	Not applicable.	
Density:Relative densityVapour densityEvaporation rate	Not determined. Not determined. Not applicable. Not applicable.	
 Solubility in / Miscibility with water at 20 °C: 	10 g/l	
· Partition coefficient: n-octanol/water:	Not determined.	
Viscosity: Dynamic: Kinematic: 9.2 Other information	Not applicable. Not applicable. No further relevant information available.	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No dangerous reactions known.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: strong oxidants
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity

Toxic if swallowed, in contact with skin or if inhaled.

· LD/LC50 values relevant for classification:

· Components	Туре	Value	Species	
Oral LD50 >50 mg/kg (rat)				

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · After inhalation: No irritant effect.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.

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- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water Danger to drinking water if even extremely small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Chemicals must be disposed of in compliance with the respective national regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport informat	ion
· 14.1 UN-Number · ADR, IMDG, IATA	UN3462
· 14.2 UN proper shipping name · ADR, IMDG, IATA	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (digitonin)
· 14.3 Transport hazard class(es)	
· ADR	
· Class · Label	6.1 (T2) Toxic substances.6.1
· IMDG, IATA	
· Class	6.1 Toxic substances.

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· Label	6.1
· 14.4 Packing group · ADR, IMDG, IATA	III
14.5 Environmental hazards:Marine pollutant:	No
14.6 Special precautions for userEMS Number:Stowage Category	Warning: Toxic substances. F-A,S-A A
 14.7 Transport in bulk according to Anne Marpol and the IBC Code 	x II of Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3462 TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (DIGITONIN), 6.1, III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · Seveso category H2 ACUTE TOXIC
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Dept. Compliance
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - Category 3

· * Data compared to the previous version altered.