

Safety Data Sheet

according to Regulation (EC) No 1907/2006

SUGI absorbent material

Revision date: 23.05.2018

Product code: 001911

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

1.1. Product identifier

SUGI absorbent material

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

Use of the substance/mixture

SUGI® absorbent material is used in various categories of surgery for absorbing blood and secretion rapidly, covering wounds and applying medication.

1.3. Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
e-mail:	info@kettenbach.com	
Contact person:	Regulatory Affairs Manager	Telephone: +49 (0)2774/705-0
Internet:	www.kettenbach.com	
Responsible Department:	Regulatory Affairs	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

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

There is no obligatory labelling requirement according to the Directive covering preparations 1999/45/EC.

2.2. Label elements

Additional advice on labelling

Product does not require special labelling according to Directive 67/548/EEC.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Composition: Cellulose approx. 35% (m/m), regenerated Cellulose approx. 65% (m/m).

Without latexes. Not from animal origin.

SECTION 4: First aid measures

4.1. Description of first aid measures

After contact with skin

Not applicable, medical device for use in surgery.

After contact with eyes

Not applicable, medical device for use in surgery.

After ingestion

not applicable

SECTION 5: Firefighting measures

5.1. Extinguishing media

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Suitable extinguishing media

Water. Foam. Carbon dioxide (CO₂).

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.
In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not required.

6.2. Environmental precautions

Not required.

6.3. Methods and material for containment and cleaning up

Take up mechanically.

6.4. Reference to other sections

No release of hazardous substances.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special precautionary measures are necessary.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Further information on handling

No special handling instructions are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Advice on storage compatibility

Do not store together with: Oxidizing agents.

Further information on storage conditions

Please pay attention to the information on the package! Keep dry, keep away from heat (temperature limitation) and direct sunlight.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

not applicable

Protective and hygiene measures

The usual precautions when handling sterile medical devices have to be obtained.

Eye/face protection

Eye protection: not required.

Hand protection

Hand protection: not required.

The usual precautions when handling sterile medical devices have to be obtained.

Skin protection

Body protection: not required.

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The usual precautions when handling sterile medical devices have to be obtained.

Respiratory protection

not applicable

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid
Colour:	white
Odour:	odourless
pH-Value (at 20 °C):	6 - 7,5

Changes in the physical state

Melting point:	Does not melt.
Softening point:	Does not soften.
Flash point:	Not applicable.
Density (at 20 °C):	ca. 1 g/cm ³
Water solubility: (at 20 °C)	< 1 g/L

9.2. Other information

Thermal decomposition: > 175°C

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

10.5. Incompatible materials

None by intended use.

10.6. Hazardous decomposition products

None by intended use.

Further information

Please pay attention to the information on the package!

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Cytotoxicity: Does not exhibit cytotoxicity.
Test according to ISO 10993-5.

Irritation and corrosivity

Irritant effect on the skin: Not an irritant. (Rabbit)
Test according to ISO 10993-10.

Irritant effect on the eye: Not an irritant. (Rabbit)
Test according to ISO 10993-10.

Sensitising effects

no danger of sensitization. (Guinea-pig.)
Test according to ISO 10993-10.

SECTION 12: Ecological information

12.2. Persistence and degradability

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Product is biodegradable.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation.

Waste disposal number of waste from residues/unused products

200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

Waste disposal number of used product

180103 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; wastes whose collection and disposal is subject to special requirements in order to prevent infection; hazardous waste

Waste disposal number of contaminated packaging

150105 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); composite packaging

Contaminated packaging

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Other applicable information

No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Water contaminating class (D): - - not water contaminating

SECTION 16: Other information

Changes

Update 2018-05-17

Further Information

@N16.P0000001 @N16.P0000002

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)