

MATERIAL SAFETY DATA SHEET

REG. (EC) No.1907/2006

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Dok.-ID:
Version: 2014-07-25
Printed: 2014-07-25

Trade Name: **GELITA-SPON® STANDARD + GELITA-SPON® RAPID³**

1. SUBSTANCE AND COMPANY NAME

General Information

Trade Name: GELITA-SPON® STANDARD + GELITA-SPON® RAPID³
Registration number: Not required
Application/Usage: Topical hemostat for use as an adjunct to hemostasis by tamponade effect
Supplier:
GELITA MEDICAL GmbH
P.O. Box 12 53
69402 Eberbach, Germany
MSDS Information: **Tel:** +49 6271 84-2021 **Email:** MSDS-info@gelita.com
Technical Information: **Tel:** +49 6271 84-2021
Emergency: **Tel:** +49 6271 84-01 (inside office hours)

2. HAZARDS IDENTIFICATION

Hazardous identification: Non Hazardous according to Directive 67/548/EEC
Additional Hazard Information for Humans or Environment: None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterisation:	Name	Fraction	CAS-Nr.	EINECS-Nr.
	Gelatine	> 99.8 %	09000-70-8	232-554-6

4. FIRST AID MEASURES

General Information: No special measures required.
After Inhalation: Not applicable.
After Skin Contact: Wash with warm water.
After Eye Contact: Remove contact lenses. Flush the eyes with water until irritation subsides.
After Ingestion: Drink water. In case of persistent symptoms consult a physician.
Additional Medical Information: In case of persistent symptoms consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable fire extinguisher: Water, powder, foam, CO₂ and sand.
Fire-fighting measures should be suited to the surroundings.
Unsuitable extinguishing agents: Not known.
Special hazards caused by the product, its products of combustion or flue gases: Product is non-flammable.
Special protective equipment for fire-fighting: No special requirements.
Additional fire-fighting information: No special requirements.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: No special measures or requirements. Good hygiene practice. Particular danger of slipping on spilled product especially if wet.
Environmental Precautions: No special measures required. Completely bio-degradable.
Clean-up Procedures: Mechanical pick-up and disposal.
Additional Information: No hazardous material is discharged.

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7. HANDLING AND STORAGE

Information for safe handling:	No special measures required. Refer to the Instructions for Use supplied with the product.
Information to fire and explosion protection:	None.
Additional Information:	None.
Storage Information:	Store odorless and dry at room temperature in its sealed protective outer packaging. Keep away from sunlight.
Requirements for storage:	Store odorless and dry at room temperature in its sealed protective outer packaging. Keep away from sunlight.
Storage Class VCI:	Not applicable.
Additional Information:	None.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limits and / or Biological Exposure Limits

Occupational Exposure Limit (AGW) Germany

Specification:	Not applicable.
Value: (Total Dust)	Not applicable.
Teratogenic:	No.

Occupational Exposure Limits in the European Union

Specification:	Not applicable.
Short Time Limit(STEL):	Not applicable.
Long Time Limit (8h TWA):	Not applicable.
Information „Skin“:	Not applicable.

Occupational Exposure Controls

General Information:	Technical measures and the application of adequate procedures (see section 7) have a higher priority than personal protective equipment. Personal protective equipment is not necessary.
Respiratory Protection:	No special measures required.
Eye Protection:	No special measures required.
Skin Protection:	If necessary use gloves e.g. cotton, latex, and nitrile rubber.
Personal Protection:	No special measures required.
Hygiene:	Sterile technique should be applied when using the product.
Environmental Protection:	See section 6 and 7. No further measures required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State:	Gelatin sponge with high porosity, several sizes.
Color:	White.
Odor:	No specific odour.

Safety Data

Explosion Hazard:	The product is not explosive
Grain Size:	Not applicable.
Median Value:	Not applicable.
Lower Explosion Limit:	Not applicable.
Maximum Explosion Pressure:	Not applicable.
Maximum Rate of Pressure Rise:	Not applicable.
Dust Explosion Capability:	Not applicable.
Minimum Ignition Energy:	Not applicable.
Minimum Ignition Temperature:	610 °C
Glow Temperature:	No smoldering until 450°C.
Burning Behavior/Rate Number	Not applicable.
Kst-Value	Not applicable.
Bulk Density	Not applicable.
Solubility:	Insoluble in water.
pH-Value:	~ 7,0

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10. STABILITY AND REACTIVITY

Conditions to avoid: See section 7
Materials to avoid: None known for intended use.
Hazardous products of decomposition: None known. CO, CO₂

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: No oral toxicity
Practical Experience: No hazards to be expected. Refer to the Instructions for Use supplied with the product.

12. ECOLOGICAL INFORMATION

Ecological Toxicity

Fish toxicity: No data available.
Aquatic Invertebrates: No data available.
Aquatic Plants: No data available.

Mobility

Persistence und Degradability: The product completely biodegradable.
Bio accumulation potential: No data available.
Determination of PBT-Characteristics: No data available.

13. DISPOSAL CONSIDERATIONS

Material / Mixture: Disposal according to local regulatory guidelines.
Recommendation: Waste code classification is to be made in accordance with the regional responsible person for waste.
Packaging: Packaging can be sent to recycling in compliance with national regulations.

14. TRANSPORT INFORMATION

Transport by Land, Air, Sea

No dangerous goods according to ADR / RID, IMDG / GGVSee, ICAO-TI / IATA-DGR

15. REGULATORY INFORMATION

Labeling/Classification according to EC Guidelines

The product is labeled as a medical device according to the Directive 93/42/EC.

Classification and Hazard Identification of Product: Not applicable.

Risk-Information: Refer to the Instructions for Use supplied with the product.
Safety-Information: Refer to the Instructions for Use supplied with the product.

National Regulations

Water Hazard Class: None. Not classified (VwVwS).
Technical Guidelines Air (TA-Luft): None.
Ordinance on Industrial Safety and Health (BetrSichV): None.
Employment Restrictions: None.
Guidelines of Accident Prevention & Insurance Associations: None.
Preventive Medical Checkup: Not applicable.

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16. OTHER INFORMATION

Other Information: None

Changes since last issue: Transfer into actual layout

The marked (*) sections of the safety data sheet have been changed compared to the last version.

The information in this material safety data sheet is based on our present state of knowledge and does not certify product characteristics. Further information is defined in the product specification and the Instructions for Use supplied with the product. The consignee of our product is responsible for complying with all relevant laws and regulations.

MSDS issued by:

GELITA MEDICAL GmbH

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