

Date of issue: 24/09/2024

Safety Data Sheet "Non Dangerous Substances"

In accordance with the Dangerous Substances Act of 1st November 1993 (91/155/EEC) EU Safety Data Sheets are provided for dangerous substances and preparations. The product mentioned herein is a non-dangerous substance. The provision of the data is not based on the guidelines 91/155/EEC and is solely for informative purposes.

## 1. Product and Company Information

1.1 Common name: Absorbable Gelatin sponge  
Commercial name: SURGISPON®

1.2 Manufacturer: AEGIS LIFESCIENCES PRIVATE LIMITED  
215/216, Mahagujarat Industrial Estate-382213, Ahmedabad,  
Gujarat, India  
Tele: +91 9726903131, 9727103131

## 2. Composition and Information on Ingredients

2.1 Components: Foam gelatin sponge  
Chemical description: Highly purified pharmaceutical grade gelatin, purified water  
2.2 Hazardous constituents: none

## 3. Possible Hazards

3.1 Hazards identification not applicable

## 4. First Aid Measures

4.1 General instructions: none  
4.2 Inhalation: not applicable  
4.3 Skin Contact: none  
4.4 Eye Contact: not applicable  
4.5 Ingestion: none  
4.6 Instructions to the Doctor: none

## 5. Fire and Explosion Data

5.1 Recommended Fire Fighting Media: no restrictions  
5.2 Proscribed Fire Fighting Media: none  
5.3 Dangerous Products of Combustion: none  
5.4 Special Protective Gear: none  
5.5 Additional Instructions: none



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## 6. Accidental Release Measures

- 6.1 Personal Safety Measures: none
- 6.2 Environmental Safety Measures: no negative ecological effects known
- 6.3 Clean-up Procedure: none
- 6.4 Additional Instructions: none

## 7. Storage and Handling

- 7.1 Handling: for professional dental/surgical use only
- 7.2 Storage: As per IFU

## 8. Exposure Controls/Personal Protection

- 8.1 Engineering Controls: none
- 8.2 Components with Specific Tolerances: none
- 8.3 Personal Protection: none

## 9. Physical and Chemical Properties

- 9.1 Form: solid, cube, sheet, sponge
  - Color: off white
  - Odour: neutral
- 9.2 Volatility: not applicable for prescribed use
- 9.3 Melting Point: none
- 9.4 Auto-Ignition Temperature: none
- 9.5 Danger of Explosion: none
- 9.6 Flash Point: none
- 9.7 Density at 20°C: none
- 9.8 Solubility in Water at 20°C: insoluble
- 9.9 pH: neutral
- 9.10 Viscosity: not applicable
- 9.11 Critical Temperature: not applicable
- 9.12 Thermal decomposition: not applicable
- 9.13 Additional Information: none

## 10. Stability and Reactivity Data

- 10.1 Conditions to avoid: no mechanical deformation
- 10.2 Substances to avoid: none
- 10.3 Dangerous decomposition products: not applicable for prescribed use
- 10.4 Additional Information: none



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### 11. Toxicological Information

11.1 Acute Toxicity: no known toxic characteristics for the product as a whole

11.2 Chronic Toxicity: none in the prescribed quantities

### 12. Ecological Information

12.1 Information for elimination: ingress in soil is harmless, biodegradable product

12.2 Behaviour in environmental compartments: neutral

12.3 Ecotoxicity: none

12.4 Additional Ecological Information: none

### 13. Disposal Considerations

13.1 Product: consult regional or local authorities

13.2 Packing: consult regional or local authorities

### 14. Transport Information

14.1 Dangerous goods: Non dangerous goods according to IATA regulations. Since the Product SURGISPON<sup>®</sup> comes under non dangerous goods the IATA regulation information is not applicable.

### 15. Regulations

15.1 Marking: not necessary

### 16. Other Information

None

This information is based on our present state of knowledge and cannot be considered as warranted quality features in legal sense. Legal regulations have to be considered on personal responsibility.

**REMARKS:** Please be advised that this agent is not subject to the Material Safety Data Sheet (MSDS) requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200). Therefore, an MSDS is not available. We ask that you refer to the MSDS for the active ingredient.

Note that our product being a medical device product exempts the REACH regulation 1907/2006. No status code is required as this product is not subjected to the provisions of Regulation (EC) No 1907/2006.



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**Annexure - I**

Common name: Absorbable Gelatin sponge  
Commercial name: SURGISPON®

Sr. No.	Product ID	Model Name	Dimensions (mm)
01	SSP-101010	DENTAL CUBES	10×10×10 mm

