

MATERIAL SAFETY DATA SHEET

Section 1 - Product and Company Information

Product Name: Axiostat®/Hemoseal® Chitosan Haemostatic Dressing

Product Code: S44, S55, M85, L88, MIL88, V55/B55, V35/B35, V25/B25, D11, N14, N18, VN22, V22/N22, M128, M2412, L55, L125, L185, L820, L1010, L2020, L3030, L50, L100, L150, L300, L370, L8100, MIL1010, MIL150, MIL185, MIL300, MIL370

Manufacturer: AXIO BIOSOLUTIONS PRIVATE LIMITED

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Ahmedabad - 382220, Gujarat, India

Emergency Health & Safety Information: +91 88607 86067, info@axiobio.com

Section 2 - Composition

1. Chitosan acetate

Section 3 - Hazards Identification

The product is a medical device and therefore not covered by the classification and labelling rules that apply to chemical products. This safety data sheet is supplied as an additional service to the customer.

Section 4 - First Aid Measures

ORAL EXPOSURE

If swallowed, drink plenty of water or milk provided the person is conscious. Do not induce vomiting.

EYE EXPOSURE

In case of contact with the eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.

Section 5 - Fire Fighting Measures

FLASH POINT: Unknown

EXPLOSION LIMIT: N/A

AUTO IGNITION: Unknown

FLAMMABILITY: N/A

EXTINGUISHING MEDIA: In case of fire, use ater, carbon dioxide, dry chemical or appropriate foam

FIREFIGHTING: Wear appropriate personal protective equipment such as self-contained breathing apparatus and protective clothing.

SPECIFIC HAZARD(S): No known hazards.

Section 6 - Accidental Release Measures

N/A

Section 7 - Handling and Storage**HANDLING:** No special handling required**STORAGE:** Storage Temperature should be in the range of 20°C to 35°C**SPECIAL:** No special handling or considerations required**Section 8 - Exposure Controls/Personal Protection****Ventilation Requirements** : Generally adequate ventilation recommended.**Exposure limit(s)** : None.**Personal protection equipment:**

- Respiratory protection: Not needed.
- Hand protection: Handle the product with Sterile Gloves
- Eye protection: Do not use over eyes.
- Skin and body protection: Not needed.

Section 9 - Physical/Chemical Properties

FORM: Chitosan Sponge
COLOR: White to off-white
MELTING POINT: N/A
BOILING POINT: N/A

Section 10 - Stability and Reactivity**STABILITY:** Stable**Conditions to Avoid:** After tearing open, immediately use for intended purpose as the product is sterile.**Materials to Avoid:** N/A**HAZARDOUS DECOMPOSITION PRODUCTS**

No hazardous decomposition products

HAZARDOUS POLYMERIZATION

Hazardous polymerization will not occur.

Section 11 - Toxicological Information**ACUTE TOXICITY:** None**LD50:** 16g/Kg (Mice)

Section 12 - Ecological Information

The entire sponge is biodegradable. No known ecological hazards.

Section 13 - Disposal Considerations

Can be disposed of by normal biodegradable waste procedure.

Section 14 - Transport Information

Material can be transported by any mode of transport.

Section 15 – Regulatory Information

The product is according to 93/42/EEC. Notifying Body: Det Norske Veritas GL business Assurance 2460

Material is listed as a carcinogen/potential carcinogen in following?: No

Section 16 – DISCLAIMER

The provided information is believed to be correct but does not purport to be all inclusive. The information in this document is based on the present state of knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Axio Biosolutions shall not be held liable for any damage resulting from handling or from contact with the above product.

Prepared by: Quality Assurance Department, Axio Biosolutions Pvt Ltd.