

MedTrade Products Limited
Product Safety Data Sheet (Confidential)

PSDS Title: CELOX Haemostatic Granules on Viscose Sheet – BULK

PSDS Number: PSDS029B

Revision: 1

1. Identification of the Substance / Preparation and the Company

Product Name: CELOX
CELOX Haemostatic Granules on Viscose Gauze

Use of the Substance: Haemostat to control life-threatening bleeding

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2. Composition / Information on Ingredients

Product Group: Haemostat on a Viscose Gauze
Non-Woven Textile

Product Codes and Descriptions: BP09934011

The haemostatic granules are made from Chitosan

Chitosan CAS number: 9012-76-4

3. Hazard Information

Most important hazards: ***Do not process large quantities if you have shellfish allergies.***

Specific Hazards: Granules Irritating to eyes and respiratory system.

In common with other textile materials there is a possibility of the fabric shedding small amounts of powder and nuisance dust.

Routes of Entry:	No health hazard is anticipated during normal handling of the product.
Carcinogenic Status:	Eye contact – Ingestion – Wounds. Not considered carcinogenic by NTP, IARC and OSHA.
Skin contact (short and long term)	This product is intended for skin contact.
Eye contact (short and long term)	Irritation, blurred vision.
Inhalation (short and long term)	May cause irritation of the mucus membranes.
Ingestion:	This product is not considered toxic, but as with any material, may be harmful if ingested in large quantities. May cause choking hazard. Do not breathe dust.

4. **First Aid measures**

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Move to fresh air. If symptoms persist, call a physician.
Eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
Ingestion:	Consult a physician. If conscious drink plenty of water. Never give anything by mouth to an unconscious person.
Protection of first-aiders:	Wear tightly fitting safety goggles. Avoid contact with eyes.
Notes to physician:	Oxygen, if needed. Chitosan is also used as a dietary aid.

5. **Fire fighting measures**

Suitable extinguishing media:	Water, carbon dioxide (CO ₂), foam, dry chemical.
Extinguishing media which Must not be used for safety reasons:	None.
Specific hazards:	When wet granules will form a viscous gel.

In common with most other textile materials, nonwoven fabrics are readily combustible when brought into contact with excessive heat or naked flame and will produce gaseous products that are harmful and should not be inhaled, use positive pressure breathing apparatus. Thermoplastic materials, which include fabrics, and some packaging material, will melt at high temperatures. The molten material should not be allowed to contact the skin, to which it may adhere, thus causing localised burns.

Special protective equipment

For fire fighters:

In the event of fire, wear self contained positive pressure breathing apparatus.

Specific methods:

Standard procedure for chemical fire. Cool containers with water spray.

6. Accidental release measures

Personal precautions:

Avoid contact with eyes and respiratory system. Wear tightly fitting safety goggles and breathing mask.

Environmental precautions:

On the basis of available information this product is not expected to produce any significant adverse environmental effects when recommended use instructions are followed. No specific measures necessary.

Methods for cleaning up:

Carefully sweep or vacuum and place into a container for disposal in accordance with local regulations.

7. Handling and storage

Technical measures / Precautions:

Avoid getting product wet.

Safe handling advice:

Storage of fabric does not constitute a fire hazard, but if involved in a fire it may emit smoke and toxic fumes.

Avoid contact with eyes and inhalation. Wear tightly fitting safety goggles and breathing mask.

Technical measures / Storage conditions:	Keep containers tightly closed.
Packaging material:	Double polyethylene bag.
Storage:	Store in a cool dry place (15° to 25°C recommended)

8. Exposure Controls / Personal protection

Engineering measures To reduce exposure:	Ensure adequate ventilation, especially in confined areas.
Exposure limit(s):	None.
Personal protection equipment:	
Respiratory protection:	Wear suitable respiratory protection if nuisance dust exposure limits are exceeded.
Hand protection:	Not normally required, but the use of light disposable gloves for protection is recommended in appropriate circumstances.
Eye protection:	Not normally required, however suitable goggles may be used.
Skin and body protection:	Long sleeved clothing.
Hygiene measures:	When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use.

9. Physical and Chemical Properties

Form:	White Nonwoven Textile Material with Straw Coloured Granules on Both surfaces.
Vapour pressure (mm Hg):	Not determined
Specific gravity:	Not determined
Water solubility:	Viscose gauze base material is insoluble in water. Granules on the surface are swellable /absorbent
Percent volatile:	Not determined
Vapour density:	N/A
Evaporation rate:	Not determined
Odour:	Negligible
Viscosity:	N/A
Odour threshold:	Unknown
Boiling point:	N/A

Freezing point: N/A
Molecular weight: N/A (cross linked polymer)

10. Stability and Reactivity

Stability Material is normally stable at moderately elevated temperatures and pressures (See above for recommended storage conditions).

11. Toxicological information

Acute toxicity: The product is considered non-toxic, when used in accordance with this information.

Irritation: The product has passed the following laboratory tests; sensitisation, irritation, cytotoxicity, acute systemic toxicity.

Local effects: Irritating to eyes. Inhalation may cause irritation of mucus membranes.

Skin contact: May cause slight skin irritation.

Eye contact: Eye irritation.

12. Ecological information

No information available on the viscous gauze. The Celox Hemostatic granules are soluble and made out of Chitosan a natural product.

13. Disposal

Contaminated packaging: No special requirements. Dispose according to local guidelines.

14. Transport Precautions

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

Viscose gauze base is non hazardous. See label below for the attached Celox Haemostatic Granules:

Celox Haemostatic Granules



R36/37 Irritating to eyes and respiratory system.

R20/22 Harmful by inhalation and if swallowed.

S25 Avoid contact with eyes.

S22 Do not breathe dust.

39 Wear eye/face protection.

16. Additional Information

The safety data sheet has been prepared in accordance with EC Directive 2001/58/EC.

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of the patient with the medical device. The information is given in good faith and is based on our present knowledge and experience.

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