

MedTrade Products Limited

Safety Data Sheet

CELOX Haemostatic Granules on Gauze / Viscose / Rayon Sheet

1. Identification

Product Name: CELOX Gauze
CELOX Roll Gauze
CELOX Z-Fold Gauze
CELOX Rapid Gauze

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

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2. Hazard Information

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.

No health hazard is anticipated during normal handling of the product.

Routes of Entry: Eye contact – Ingestion – Wounds.

Carcinogenic Status: 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.

3. Composition / Information on Ingredients

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

Product Codes and Descriptions: FG08834011 – CELOX Gauze 10ft Roll
FG08838011 - CELOX Gauze 10ft Z-Fold
FG08838013 – CELOX Gauze 5ft Z-Fold
FG08839011 – CELOX Rapid

The haemostatic granules are made from Chitosan

Chitosan CAS number: 9012-76-4

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: 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 (CO₂), 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

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.

Technical measures /
Storage conditions:

Keep tightly closed.

8. Exposure Controls / Personal protection

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|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Engineering measures To reduce exposure: | Ensure adequate ventilation, especially in confined areas. |
| Exposure limit(s): | None. |
| Personal protection equipment: | None |
| Respiratory protection: | None |
| 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: | None |
| Hygiene measures: | When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use. |

9. Physical and Chemical Properties

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| 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

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| Stability | Material is normally stable at moderately elevated temperatures and pressures |
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11. Toxicological information

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| 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

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| Contaminated packaging: | No special requirements. Dispose according to local guidelines. |
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14. Transport Precautions

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

Product has regulatory approval in Europe & USA as a Medical Device

16. Additional Information

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

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