

SAFETY DATA SHEET

(REACH Regulation (EC) N° 1907/2006 - N° 453/2010)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE

1.1. Product Identifier

- Product Name: **Celox Granules and Celox Applicator**
- Product Code: FG04630541, FG05130501, FG05132061A, FG05832101, FG08830181, FG08830361, FG08830391, FG08830441, FG08830551, FG08830521, FG08832021, FG08832041A, FG08832071A, FG08830241

1.2. Relevant identified uses of the substance or mixture and uses advised against

Product used as a haemostat. All indications and contraindications listed on IFU

1.3. Details of the supplier of the safety data sheet

- Registered company name: Medtrade Products Limited
- Address: Electra House, Electra way, Crewe, CW1 6GL
- Telephone: 01270 500019
- Email: celoxenquiries@medtrade.co.uk

1.4. Emergency telephone number:

- Ian Walker (+44(0)1270503886)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments

- No data available
- This mixture does not present a physical hazard. Refer to recommendation regarding the other products present on the site

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments

- Hazard pictograms: N/A
- Product identifiers: N/A
- Hazard statements: No data available
- Precautionary statements – Prevention: No data available
- Precautionary statements – Response: No data available

2.3. Other hazards

- No data available

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

- No substances fulfil the criteria set forth in Annex II section A of the Reach regulation (EC) N° 1907/2006

3.2. Mixtures

Composition:

Identification	Name	Classification	%
CAS: 9012-76-4	Chitosan	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008	Proprietary
N/A	Chitosan Derivative	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008	Proprietary

SECTION 4: FIRST AID MEASURES

- As a general rule, in case of doubt or if symptoms persist, always call a doctor
- NEVER induce swallowing in an unconscious person
- Product is derived from shellfish and so persons with known sensitivity to shellfish may experience allergic reaction or anaphylactic shock.

4.1. Description of first aid measures

In the event of exposure by inhalation:

- No data available

In the event of exposure to eyes:

- Wash thoroughly with soft, clean water for 15 minutes holding eyelids open
- If there is any redness, pain or visual impairment, consult ophthalmologist

In the event of swallowing:

- Do not give the patient anything orally
- In the event of swallowing, rinse mouth with water and consult doctor
- Seek medical attention immediately, showing label

4.2. Most important symptoms, both acute and delayed

- No data available

4.3. Indication of any immediate medical attention and special treatment needed

- No data available

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SECTION 5: FIREFIGHTING MEASURES

- Non flammable

5.1. Extinguishing media

- In the event of fire, use specifically suitable extinguishing agents. Never use water.

Suitable methods of extinction

- In the event of fire use:
 - Dry chemical agents
 - Foam
 - Carbon dioxide

5.2. Special hazards arising from the substance or mixture

- A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health
- Do not breathe in smoke

5.3. Advice for firefighters

- Due to the toxicity of the gas emitted on thermal decomposition, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Use appropriate personal protective equipment. For personal protection see section 8.

6.2 Environmental precautions

- Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

- Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

- For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

- Requirements relating to storage premises apply to all facilities when the mixture is handled
- Individuals with a history of skin sensitisation should not, under any circumstances handle the product

7.1. Precaution for safe handling

- Always wash hands after handling
- Remove and wash contaminated clothing before re-using

7.2. Conditions for safe storage, including incompatibilities

- Store in ambient conditions

Storage: Keep out of direct heat

Packaging: Moisture impermeable tear pouches (Foil)

7.3. Specific end use(s)

- Medical Device for use by trained emergency responders
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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

- No data available

8.2. Exposure Controls

Personal protection measures, such as personal protective equipment

- Use personal protective equipment that is clean and has been properly maintained
 - Store personal protective equipment in clean dry place, away from work area
 - Never eat, drink or smoke during application.
- **Eye/Face protection**
- Avoid contact with eyes
 - Prescription glasses are not considered protection
 - Provide eyewash station in facilities where the product is handled constantly
- **Hand protection**
- Use suitable gloves that are resistant to chemical agents in accordance with standard BSEN16523-1
 - Gloves must be selected according to application and duration of use
 - Protective gloves must be selected according to their suitability for the workstation in question: other products may be handled, necessary physical protections, level of dexterity required
- **Body protection**
- Wear suitable protective clothing
 - Work clothing worn by personnel shall be laundered regularly
 - After contact with the product, all parts of the body that have been soiled must be washed
- **Respiratory Protection**
- No data available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Physical state:	Solid material in powder form
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Important health, safety and environmental information:

pH of the substance or preparation	5-7
Flash point interval	Not relevant
Vapour pressure	Not relevant
Density	Not relevant
Water solubility	Soluble

9.2. Other information

- Product is derived from shellfish.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

- No data available

10.2. Chemical stability

- The mixture is stable under the recommended handling and storage conditions in section 7

10.3. Possibility of hazardous reactions

- No data available

10.4. Conditions to avoid

- Excessive Heat

10.5. Incompatible materials

- None known

10.6. Hazardous decomposition products

- The thermal decomposition may release/form: Unknown
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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Mixture

- No toxicological data available for the mixture

Skin corrosion/skin irritation:

- Product is a medical device and has passed skin irritation and sensitisation in accordance with ISO1010103
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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Substances

- No toxicity data available for the substances

Mixtures

- No toxicity data available for the mixture

12.2. Persistence and degradability

- No data available

12.3. Bioaccumulative potential

- No data available

12.4. Mobility in soil

- No data available

12.5. Results if PBT and vPvB assessment

- No data available

12.6. Other adverse effects

- No data available
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SECTION 13: DISPOSAL CONSIDERATIONS

- Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/108/EC

13.1. Waste treatment methods

Waste:

- Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, soil, plants and animals
- Recycle or dispose of waste in compliance with current legislation, preferably via certified collector or company
- Do not contaminate the ground or water with waste, do not dispose of waste into environment

Solid Packaging

- Empty container completely. Keep label(s) on container
 - Give to a certified disposal contractor
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SECTION 14: TRANSPORT INFORMATION

- No special instructions
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SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Particular provisions

- No data available

15.2. Chemical safety assessment

- No data available
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SECTION 16: OTHER INFORMATION

- Since the user's working conditions are not known by us, the information supplied on this safety sheet is based on our current level of knowledge and on national and community regulations
- The mixture must not be used for other uses than those specified in section 1 without have first obtained written handling instructions
- It is at all time the responsibility of the user to take all necessary measures to comply with the legal requirements, local regulations and in compliance with the products IFU.
- The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof