

SAFETY DATA SHEET

PROMOGRAN Prisma*



This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This Safety Data Sheet is provided as a courtesy to the customer, as this product is not hazardous under foreseeable conditions of use.

1. Identification of the Substance/Mixture and of the Company/Undertaking

Identification of the substance or preparation

PROMOGRAN Prisma*

Use of the substance/preparation

Wound dressing

Company/undertaking identification

Systagenix Wound Management
Gargrave
North Yorkshire BD23 3RX
United Kingdom

Phone: +44 (0)1756 747200

2. Hazards Identification

This product is not expected to be hazardous under foreseen conditions of use. However, as with all health care products, care should be taken to carefully read the instructions before use.

3. Composition/Information on ingredients

A light, off-white, open-pored, freeze dried hexagonal pad of 55% collagen, 44% oxidized regenerated cellulose (ORC) and 1% silver-ORC.

4. First Aid Measures

Inhalation

Inhalation is not expected to occur.

Skin contact

No effects from skin contact are anticipated. Wash skin with plenty of soap and water.

Accidental eye contact

No effects from eye contact are expected. Rinse eye with plenty of water.

Ingestion

Ingestion is not expected to occur.

Notes to doctor/physician

None.

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5. Firefighting Measures

Recommended extinguishing media

No known adverse reactions with any extinguishing media. Use extinguisher appropriate to surrounding conditions.

Special exposure hazards (from the material or its combustion products)

Normal combustion products are considered to be carbon dioxide, although incomplete combustion may lead to the formation of organic decomposition products.

Special precautions for fire fighters

No special precautions required. Wear normal fire-fighting kit and breathing apparatus as appropriate.

6. Accidental Release Measures

Personal precautions

No special precautions required.

Environmental precautions

No special precautions required.

Methods for cleaning up

Unused dressings should be collected and disposed of according to local and national regulations.

Used dressing should be collected and disposed of as clinical waste.

7. Handling and Storage

Handling

Normal sterile working procedures will provide adequate protection.

Storage

Store in a cool, dry place. Avoid extremes of temperature.

Specific uses

None.

8. Exposure Controls/Personal Protection

Exposure limit values

None.

Occupational exposure controls

Respiratory protection

No special precautions required.

Eye protection

No special precautions required.

Skin protection

Surgical gloves should be worn in accordance with normal working procedures.

Environmental exposure controls

None required.

9. Physical and Chemical Properties

General information

Appearance Off-white hexagonal pad

Important health, safety and environmental information

pH Not applicable
Boiling point / range Not applicable
Flash point Not applicable
Vapour pressure Not applicable
Relative Density Not applicable
Water solubility Forms a gel in contact with water
Partition coefficient (log Kow) Not applicable

Other information

Autoignition temperature Not determined

10. Stability and Reactivity

Conditions to avoid

Avoid extremes of temperature.

Materials to avoid

Avoid contact with strong oxidizing agents.

Hazardous decomposition products

Normal combustion products.

11. Toxicological Information

Eye effects: No effects on the eye are anticipated from the product as supplied.

Skin effects: No effects on the skin are anticipated from the product as supplied. PROMOGRAN Prisma** should not be used on individuals with known sensitivity to collagen, oxidised regenerated cellulose (ORC), or silver.

Inhalation: No effects from inhalation are anticipated from the product as supplied.

Ingestion: No effects from ingestion are anticipated from the product as supplied.

12. Ecological Information

Not expected to be hazardous to the environment.

Ecotoxicity Not determined
Mobility Not determined
Persistence and degradability Not determined
Bioaccumulation potential Not determined
Results of PBT assessment Not determined
Other adverse effects Not determined

13. Disposal Considerations

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Disposal should be in accordance with local and national regulations.

14. Transport Information

Not regulated as hazardous for transport.

15. Regulatory Information

This product is not considered hazardous according to supply regulations.

16. Other Information

Approved for use as a medical device. Refer to full Instructions For Use.

Uses advised against: this product is only supplied for professional use as a medical device.

Special training: no specialist training required with respect to chemical hazards

Phrases used in Section 3

None

Revision information: This is a new Safety Data Sheet.