

# SAFETY DATA SHEET



## PROMOGRAN PRISMA® Wound Balancing Matrix & PROMOGRAN® PLUS Wound Balancing Matrix & PROMOGRAN PRISMA® Matrix

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 information must be made available to those who may come into contact with the material or are responsible for the use of the material. This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006, and described in CLP Regulation (EC) No 1272/2008.

### **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

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- 1.1 Product identifier**  
PROMOGRAN PRISMA® Wound Balancing Matrix & PROMOGRAN® PLUS Wound Balancing Matrix & PROMOGRAN PRISMA® Matrix
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
Wound dressing. This product is only supplied for professional use as a medical device.
- 1.3 Details of the supplier of the safety data sheet**  
Systagenix Wound Management Ltd.  
Gargrave  
North Yorkshire BD23 3RX  
United Kingdom  
Phone: +44 (0)1756 747200  
Email: (UK): [customer-careuk@systagenix.com](mailto:customer-careuk@systagenix.com)  
(US): [nccorderdocintake@acelity.com](mailto:nccorderdocintake@acelity.com)
- 1.4 Emergency telephone number**  
**In case of emergency Tel.** (UK): 0800-917-5403 / 020-3027-8716 (Mon-Fri 09.00-17.00hrs)  
(US): 1-800-275-4524 (Mon-Fri 8:00am EST – 5:00pm EST)

### **SECTION 2: Hazards Identification**

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- 2.1 Classification of the substance or mixture**  
This product is not classified as hazardous in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).
- 2.2 Label elements**  
No labelling is required in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).
- 2.3 Other hazards**  
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.

### **SECTION 3: Composition / information on ingredients**

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- 3.1 Substances**  
Not applicable. Product is not a substance.

### 3.2 Mixtures

PROMOGRAN PRISMA® Wound Balancing Matrix & PROMOGRAN® PLUS Wound Balancing Matrix & PROMOGRAN PRISMA® Matrix is a light, off-white, open-pored, freeze dried hexagonal pad of 55% collagen, 44% oxidized regenerated cellulose (ORC) and 1% silver-ORC.

## **SECTION 4: First Aid Measures**

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### 4.1 Description of first aid measures

**EYE CONTACT:** Rinse eye with plenty of water.  
**INHALATION:** Inhalation is not likely to occur.  
**SKIN CONTACT:** Wash skin with plenty of soap and water.  
**INGESTION:** Ingestion is not likely to occur.

### 4.2 Most important symptoms and effects, both acute and delayed

No effects from skin or eye contact are anticipated.

### 4.3 Indication of any immediate medical attention and special treatments needed

Symptomatic treatment as required

## **SECTION 5: Firefighting Measures**

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### 5.1 Extinguishing media

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

### 5.2 Special hazards arising from the substance or mixture

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

### 5.3 Advice for fire fighters

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

## **SECTION 6: Accidental Release Measures**

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### 6.1 Personal precautions, protective equipment and emergency procedures

No special precautions required for unused dressings.

### 6.2 Environmental precautions

No special precautions required.

### 6.3 Methods and materials for containment and clearing 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.

### 6.4 References to other sections

None.

## **SECTION 7: Handling and Storage**

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### 7.1 Precautions for safe handling

Normal sterile working procedures will provide adequate protection.

### 7.2 Conditions for safe storage, including any incompatibilities

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

### 7.3 Specific end uses(s)

None

## **SECTION 8. Exposure Controls/Personal Protection**

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### **8.1 Control parameters**

No exposure limits applicable

### **8.2 Exposure controls**

Engineering controls are not required.

#### **Respiratory protection**

No special precautions required. Inhalation is not likely to occur.

#### **Hand Protection**

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

#### **Eye protection**

No special precautions required.

#### **Skin protection**

No special precautions required.

#### **Environmental exposure controls**

None required.

## **SECTION 9: Physical and Chemical Properties**

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### **9.1 Information on basic physical and chemical properties**

<b>Appearance:</b>	Off-white hexagonal pad
<b>Odour:</b>	None
<b>Odour threshold:</b>	Not applicable
<b>pH:</b>	Not applicable
<b>Melting point:</b>	Not applicable
<b>Boiling point:</b>	Not applicable
<b>Flashpoint:</b>	Not applicable
<b>Evaporation rate:</b>	Not applicable
<b>Flammability:</b>	Combustible
<b>Upper/lower flammability limits:</b>	Not applicable
<b>Vapour pressure:</b>	Not applicable
<b>Vapour density</b>	Not applicable
<b>Relative density</b>	Not applicable
<b>Solubility in water:</b>	Forms a gel in contact with water
<b>Solubility in other solvents:</b>	Not applicable
<b>Partition coefficient (log Kow)</b>	Not applicable
<b>Autoignition temperature</b>	No data
<b>Decomposition temperature</b>	No data
<b>Viscosity</b>	Not applicable
<b>Explosive properties</b>	Not considered explosive
<b>Oxidising properties</b>	Not considered oxidising

### **9.2 Other information**

None

## **SECTION 10: Stability and Reactivity**

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### **10.1 Reactivity**

No reactive hazards known.

### **10.2 Chemical stability**

Stable under normal conditions of use.

### 10.3 Possibility of hazardous reactions

No hazardous reactions expected.

### 10.4 Conditions to avoid

Avoid extremes of temperature

### 10.5 Incompatible materials

Avoid contact with strong oxidizing agents

### 10.6 Hazardous decomposition products

Normal combustion products.

## **SECTION 11: Toxicological Information**

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### 11.1 Information on toxicological effects

This product has not been tested. Judgements on the expected toxicity of this product have been made based upon consideration of its major components.

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|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (a) acute toxicity                 | No effects are anticipated from the product as supplied.                                                                                                   |
| (b) skin corrosion/irritation      | No effects are anticipated from the product as supplied.                                                                                                   |
| (c) serious eye damage/irritation  | No effects are anticipated from the product as supplied.                                                                                                   |
| (d) respiratory/skin sensitisation | PROMOGRAN PRISMA® / PROMOGRAN® PLUS should not be used on individuals with known sensitivity to collagen, oxidised regenerated cellulose (ORC), or silver. |
| (e) germ cell mutagenicity         | Contains no known mutagens                                                                                                                                 |
| (f) carcinogenicity                | Contains no known carcinogens                                                                                                                              |
| (g) reproductive toxicity          | Contains no known reproductive toxins                                                                                                                      |
| (h) STOT-single exposure           | No effects are anticipated from the product as supplied.                                                                                                   |
| (i) STOT-repeated exposure         | No effects are anticipated from the product as supplied.                                                                                                   |
| (j) aspiration hazard              | Not applicable to this product                                                                                                                             |

## **SECTION 12: Ecological Information**

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### 12.1 Toxicity

No effects are anticipated from the product as supplied.

### 12.2 Persistence and degradability

This product is expected to biodegrade slowly in the environment.

### 12.3 Bioaccumulative potential

None of the components are known to be bioaccumulative.

### 12.4 Mobility in soil

Not expected to be mobile.

### 12.5 Results of PBT and vPvB assessment

None of the components are known to be PBT or vPvB.

### 12.6 Other adverse effects

None known.

## **SECTION 13: Disposal Considerations**

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### 13.1 Waste treatment methods

Disposal should be in accordance with local and national regulations.  
Used dressings should be disposed of as clinical waste.

#### **SECTION 14: Transport Information**

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Not regulated as hazardous for transport.

	ADR	IMDG	ICAO
14.1 UN Number	None	None	None
14.2 UN Proper shipping name	None	None	None
14.3 Transport hazard class(es)	None	None	None
14.4 Packing group	None	None	None
14.5 Environmental hazards	None	None	None
14.6 Special precautions for user	None	None	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	None	None	None

#### **SECTION 15: Regulatory Information**

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

All components are listed as existing substances in Europe

##### **15.2 Chemical Safety Assessment**

A Chemical Safety Assessment has not been carried out for this product.

#### **SECTION 16: Other Information**

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**Revision information:** Update to US contact details.

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

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

##### **List of Abbreviations used in this SDS:**

CAS Chemical Abstracts Service  
CLP Classification, Labelling and Packaging Regulation (EC) no 1272/2008  
DSD Dangerous Substances Directive 67/548/EEC  
DPD Dangerous Preparations Directive 1999/45/EC  
EC European Community/Commission  
PBT Persistent, Bioaccumulative and Toxic  
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006  
vPvB very Persistent, very Bioaccumulative