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

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): customercareuk@systagenix.com
(US): 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

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

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

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

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

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

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

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

9.1 Information on basic physical and chemical properties

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

9.2 Other information
None

SECTION 10: Stability and Reactivity

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

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.

(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

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

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

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

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

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