

Safety Data Sheet

Issue Date: APRIL 2019

MKT.1469.01

Endoform® Antimicrobial Dermal Template

1. SECTION 1: IDENTIFICATION

1.1. PRODUCT IDENTIFIER

Product Form: Mixture

Product Name: Endoform® Antimicrobial Dermal Template

Product Code(s): 629311, 629312, 629313, 629314

1.2. INTENDED USE OF THE PRODUCT

Management of acute and chronic wounds

1.3. NAME, ADDRESS AND TELEPHONE OF THE RESPONSIBLE PARTY

Manufacturer:

Aroa Biosurgery Limited

2 Kingsford Smith Place, Airport Oaks, 2022

New Zealand

Distributor:

Appulse Medical LLC.

340 Progress Drive, Manchester, CT 06042

United States

Emergency Telephone Number

Emergency Number: 1-860-337-7730

2. SECTION 2: HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification (GHS-US): No classification

2.2. LABEL ELEMENTS

GHS-US Labelling: There are no hazardous ingredients as defined in the United States 29 CFR 1910.1200 (OSHA) or the Canadian Controlled Products Regulations (WHMIS) and therefore not subject to the labelling requirements of the aforementioned standards.

2.3. OTHER HAZARDS

No additional information available

2.4. UNKNOWN ACUTE TOXICITY (GHS-US)

No data available

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. SUBSTANCES

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS					
HAZARDOUS COMPONENT (Specific chemical identity, common name(s))	CAS #	OSHA PEL	ACGIH TLV	OTHER LIMITS RECOMMENDED	% (optional)
Collagen (freeze-dried)	9064-67-9	NA	NA	NA	
Ionic silver	7761-88-8	NA	NA	NA	

4. SECTION 4: FIRST AID MEASURES

4.1. DESCRIPTION OF THE FIRST AID MEASURES

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Inhalation: remove to fresh air, and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

Skin Contact: Rinse immediately with water if irritation develops. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 15 mins. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Do not induce vomiting. Rinse mouth. Seek medical attention if a large amount is swallowed.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS BOTH ACUTE AND DELAYED

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: May cause respiratory irritation.

Eye Contact: May cause eye irritation.

Ingestion: Ingestion is not likely to be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

If you are unwell, seek medical advice (show the label if possible).

5. FIRE FIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media: Use extinguishing media appropriate for the surrounding fire.

Unsuitable extinguishing media: Do not use heavy water stream. Heavy water stream may spread fire.

5.2. SPECIALS HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions of use.

5.3. ADVICE FOR FIREFIGHTERS

Precautionary measures Fire: Exercise caution when fighting any chemical fire.

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Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Sodium oxides. Phosphorous oxides. Chlorine gas. Nitrogen oxides.

5.4. REFERENCE TO OTHER SECTIONS

Refer to Section 9 for flammability properties.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

General Measures: None required during normal under normal conditions of use.

6.1.1. For Non-Emergency Personnel

Protective Equipment: None required during normal under normal conditions of use.

Emergency Procedures: None required during normal under normal conditions of use.

6.1.2. For Emergency Personnel

Protective Equipment: None required during normal under normal conditions of use.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. ENVIRONMENTAL PRECAUTIONS

Prevent entry to sewers and public waters.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

For Containment: sweep up and place in suitable, closed containers for disposal. Clean surfaces thoroughly with water to remove residual contamination. Dispose of all waste and cleanup materials in accordance with regulations.

Methods for Cleaning Up: clear up spills immediately and dispose of waste safely and in accordance with applicable regulations. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

7. SECTION 7: HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Technical Measures: comply with applicable regulations.

Storage Conditions: store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

7.3. SPECIFIC END USE(S)

No use is specified.

8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

8.2. EXPOSURE CONTROLS

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity. Ensure all national/local regulations are observed.

Personal Protective Equipment: None required during normal under normal conditions of use.

Materials for Protective Clothing: None required during normal under normal conditions of use.

Hand Protection: None required during normal under normal conditions of use.

Eye Protection: None required during normal under normal conditions of use.

Skin and Body Protection: None required during normal under normal conditions of use.

Respiratory Protection: None required during normal under normal conditions of use.

Environmental Exposure Controls: None required during normal under normal conditions of use.

Consumer Exposure Controls: Do not eat, drink or smoke during use.

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid
Appearance:	White to cream colored sheet
Odor:	None
Odor Threshold:	Not available
pH:	pH=7.0 (hydrated)
Evaporation Rate:	Not available
Melting Point:	Not available
Freezing Point:	Not available
Boiling Point:	Not available
Flash Point:	Not available
Auto-ignition Temperature:	Not available
Decomposition Temperature:	Not available
Flammability (solid, gas):	Not available
Lower Flammable Limit:	Not available
Upper Flammable Limit:	Not available
Vapor Pressure:	Not available

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Relative Vapor Density at 20 °C:	Not available
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Specific Gravity:	Not available
Solubility:	Insoluble in water
Partition Coefficient: N-Octanol/Water:	Not available
Viscosity:	Not available
Explosion Data – Sensitivity to Mechanical Impact:	Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge:	Not expected to present an explosion hazard due to static discharge.

10. SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY

Hazardous reactions will not occur under normal conditions.

10.2. CHEMICAL STABILITY

Stable under recommended handling and storage conditions (see section 7).

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

Hazardous polymerization or reactions will not occur.

10.4. CONDITIONS TO AVOID

Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials. Store per the directions provided in the labelling.

10.5. INCOMPATIBLE MATERIALS

Strong acids, strong bases, strong oxidizers.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

None known.

11. TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS – PRODUCT

Acute Toxicity:	Non-toxic
LD50 and LC50 Data:	Not available
Skin Corrosion/Irritation:	Non-irritant
Serious Eye Damage/Irritation:	Not classified
Respiratory or Skin Sensitization:	Non-sensitizer (skin)
Germ Cell Mutagenicity:	Non-mutagenic
Teratogenicity:	Non-teratogenic
Carcinogenicity:	Non-carcinogenic
Specific Target Organ Toxicity (Repeated Exposure):	Not classified
Reproductive Toxicity:	Not classified
Specific Target Organ Toxicity (Single Exposure):	Not classified
Aspiration Hazard:	Not classified
Symptoms/Injuries After Inhalation:	Unlikely to cause respiratory irritation under normal conditions of use
Symptoms/Injuries After Skin Contact:	Unlikely to cause skin irritation
Symptoms/Injuries After Eye Contact:	May cause eye irritation
Symptoms/Injuries After Ingestion:	Ingestion is unlikely to be harmful or have any adverse effects
Chronic Symptoms:	None expected under normal conditions of use

11.2. INFORMATION ON TOXICOLOGICAL EFFECTS - INGREDIENT(S)

LD50 and LC50 Data:	Not available
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12. SECTION 12: ECOLOGICAL INFORMATION

12.1. TOXICITY

No additional information available

12.2. PERSISTENCE AND DEGRADABILITY

Not available

12.3. BIOACCUMULATIVE POTENTIAL

Not available

12.4. MOBILITY IN SOIL

Not available

12.5. OTHER ADVERSE EFFECTS

Not available

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

14. SECTION 14: TRANSPORT INFORMATION

14.1. IN ACCORDANCE WITH DOT

Not regulated for transport

14.2. IN ACCORDANCE WITH IMDG

Not regulated for transport

14.3. IN ACCORDANCE WITH IATA

Not regulated for transport

14.4. IN ACCORDANCE WITH TDG

Not regulated for transport

15. SECTION 15: REGULATORY INFORMATION**15.1. US FEDERAL REGULATIONS**

Exempt from United States Toxic Substances Control Act (TSCA) regulation (40 CFR 710).

15.2. US STATE REGULATIONS

The product and/or components do not appear on any state Right to Know lists. This product does not contain chemicals listed in the Safe Drinking Water and Toxic Enforcement Act of 1986 ('PROP 65').

15.3. CANADIAN REGULATIONS

The product and/or components do not appear on the Domestic Substances List (DSL) and/or the Non-Domestic Substances List (NDSL). The product and/or components do not appear on the Canadian Hazardous Products Act Ingredient Disclosure List.

15.4. EUROPEAN REGULATIONS

This product is not classified according to the EU regulations DSCL (EEC). This material is not classified as Dangerous according to the health and physical properties criteria of the EU Directives on the classification of substances and preparation.

16. SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : April 2019

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Party Responsible for the Preparation of this Document: Aroa Biosurgery Limited, Auckland, New Zealand.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.