

## SAFETY DATA SHEET



### 1. PRODUCT AND COMPANY IDENTIFICATION

#### Product Identifier

Material: Purified Collagen (Type I porcine pericardium)  
Trade Name: Collaflex® collagen membrane  
Synonyms: barrier membrane, guided tissue regeneration membrane  
Chemical Family: Not applicable

#### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Medical device

#### Details of the Supplier of the Safety Data Sheet

Unicare Biomedical, Inc.  
23011 Moulton Parkway, J-11  
Laguna Hills, CA 92653 USA  
Emergency Telephone Number: 1-949-305-9600  
Contact e-Mail: sales@unicarebiomedical.com

### 2. HAZARDS IDENTIFICATION

#### Classification of the Substance or Mixture

GHS – Classification: Non- hazardous  
EU Classification:  
EU Indication of danger: Not classified

#### Label Elements

Signal Word: Not applicable  
Hazard Statements: Not classified in accordance with international standards for workplace safety.

**Other Hazards:** Not a hazardous substance or mixture

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU Classification	GHS Classification	%
Type I Collagen from porcine pericardium	9007-34-5	Not listed	Not listed	100

## 4. FIRST AID MEASURES

### Description of First Aid Measures

*General:* Never give anything by mouth to an unconscious person. If they feel unwell, seek medical attention. This product should not be used in patients with a known allergy against collagen and in the presence of infected wounds.

*Eye Contact:* Flush eye(s) immediately with plenty of water. Remove contact lenses, if present and easy to remove. If irritation occurs or persists, seek medical attention.

*Skin Contact:* Thoroughly wash skin with soap and water. If irritation occurs or persists, seek medical attention.

*Ingestion:* Do not induce vomiting. Rinse their mouth. Consult a physician or seek medical attention if necessary.

*Inhalation:* Due to the intraoral nature of this material, first aid is not normally required. Remove patient to fresh air and keep in a comfortable resting position for breathing. If discomfort or breathing difficulty occurs, seek medical attention.

### Most Important Symptoms and Effects, both Acute and Delayed

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

*Eye Contact:* May cause eye irritation.

*Skin Contact:* May cause skin irritation.

*Ingestion:* Ingestion is unlikely to be harmful or have adverse effects.

*Inhalation:* May cause respiratory irritation.

### Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician: If the patient feels unwell, seek medical advice and show the labels where possible.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish surrounding fires with the appropriate media e.g. CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

Hazardous thermal decomposition products: Hazardous reactions will not occur under normal conditions.

Fire / Explosion Hazards: Product is not flammable or explosive

**Advice for Fire-Fighters:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

## Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** This is a solid membrane for medical implantation use. It does not spill. The membranes can be collected by gloved hands and can be disposed of with normal clinical waste, but note that local and national regulations must also be observed.

**Additional Consideration for Large Spills:** This is a solid membrane for medical implantation use. It does not spill. The membranes can be collected with gloved hands.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Hygiene measures: Handle in sterile environment in accordance to dental hygiene and safety procedures.

### Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store in a dry, cool and well ventilated room between 1 and 30°C. Keep in properly labeled containers. Keep away from direct sunlight and heat.

**Specific end use(s):** Medical device for licensed professionals

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

### Exposure Controls

**Engineering Controls:** General room ventilation is adequate unless the process generates dust, mist or fumes.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear chemically resistant protective gloves.

**Eyes:** Not required under normal conditions of use.

**Skin:** Wear appropriate protective clothing.

**Respiratory protection:** Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Solid

**Appearance:** White, fibrous membrane

**Odor:** Not available

**Odor Threshold:** Not available

**pH:** Not available

**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  
**Relative Vapor Density at 20 °C:** Not available  
**Relative Density:** Not available  
**Specific Gravity:** Not available  
**Solubility:** Not available  
**Partition Coefficient:** N-Octanol/Water: Not available  
**Viscosity:** Not available  
**Explosion Data – Sensitivity to Mechanical Impact:** Not applicable  
**Explosion Data – Sensitivity to Static Discharge:** Not applicable

## 10. STABILITY AND REACTIVITY

**Reactivity:** No decomposition or hazardous reactions under ambient conditions.  
**Chemical Stability:** Stable under recommended conditions of use (see section 7).  
**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur under normal conditions.  
**Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.  
**Incompatible materials:** Strong acids, strong bases, oxidizers  
**Hazardous Decomposition Products:** None known.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** This product is composed of non-hazardous ingredients.  
**Carcinogen Status:** The components used in this product are not listed as a human carcinogen by IARC, NTP or US OSHA.

**Acute Toxicity:** Not available  
**LD50 and LC50 Data:** Not available  
**Skin Corrosion/Irritation:** Not classified  
**Serious Eye Damage/Irritation:** Not classified  
**Respiratory or Skin Sensitization:** Not classified  
**Germ Cell Mutagenicity:** Not classified  
**Teratogenicity:** Not classified  
**Carcinogenicity:** Not classified  
**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:** May cause respiratory irritation  
**Symptoms/Injuries After Skin Contact:** May cause skin irritation  
**Symptoms/Injuries After Eye Contact:** May cause eye irritation  
**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects  
**Chronic Symptoms:** None expected under normal conditions of use

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Collagen is one of the most thoroughly researched natural biomaterials. There are no environmental hazards.

**Aquatic Toxicity:** The substance is a natural polymer and is not expected to produce toxic effects.

**Additional ecological information:** The product contains no substances classified as hazardous to the environment in concentrations which should be taken into account.

**Bio-accumulative Potential:** No data available. The material is biodegradable.

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**OSHA Label:** Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

**WHMIS hazard class:** None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

**CERCLA/SARA 313 Emission reporting:** Not Listed

**California Proposition 65:** Not Listed

**Inventory - United States TSCA - Sect. 8(b):** Present

Australia (AICS): Present

## 16. OTHER INFORMATION

Data Sources: Unicare Biomedical, Inc. proprietary device development information.

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Prepared by: Operations Department, Unicare Biomedical, Inc.

*Unicare Biomedical, Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.*

End of Safety Data Sheet