

SAFETY DATA SHEET



1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Material Name: Polylactide and Polyglycolide copolymer
Trade Name: Cytoflex Resorb membrane
Synonyms: Resorbable synthetic membranes
Chemical Family: Polylactide, Polyglycolide

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
1-949-305-9600
Emergency Telephone Number: 1-949-305-9600
Contact e-Mail: sales@unicarebiomedical.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS – Classification: Not classified as hazardous
EU Classification:
EU Indication of danger: Not classified

Label Elements

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

Other Hazards: No data available

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	%
Polylactide	26100-51-6	Not listed	Not listed	~50
Polyglycolide	26009-03-0	Not listed	Not listed	~50

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: No hazards which require special first aid measures. Wash off with soap and water. Cool skin rapidly with cold water after contact with molten material. Do not peel polymer from the skin. Consult a physician.

Ingestion: Not a probable route of exposure. However, in case of accidental ingestion, call a physician.

Inhalation: Not a probable route of exposure. Due to the nature of this material first aid is not normally required. If discomfort occurs, get medical attention.

Most Important Symptoms and Effects, both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous thermal decomposition products: None known

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

No special environmental precautions required.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special handling requirements for normal use of this material.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Medical device

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: Under normal conditions of use, personal protective equipment is not expected to be necessary.

Hands: Under normal conditions of use, hands protection is not expected to be necessary.

Eyes: Under normal conditions of use, eye protection is not expected to be necessary.

Skin: Under normal conditions of use, skin protection is not expected to be necessary.

Respiratory protection: Under normal conditions of use, respiratory protection is not expected to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

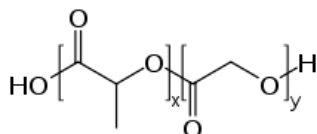
Physical State: Solid membrane

Color: White

Odor: None

Odor Threshold: No data available

Structure of poly(lactic-co-glycolic acid). x= number of units of lactic acid; y= number of units of glycolic acid.



Molecular Formula:

Nominal formula Weight: Not applicable

pH: No data available

Water Solubility: Not soluble

Solvent Solubility: Soluble in acid solution

Melting/Freezing Point (°C): 150°C -160°C

Boiling Point (°C): No data available

Viscosity: No data available

Density: ~0.8 gram/ml

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Evaporation Rate (Gram/s): No data available

Form: Solid membrane

Partition Coefficient: (Method, pH, Endpoint, Value) No data available.

Decomposition Temperature (°C): No data available.

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No decomposition if stored at ambient conditions.

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions: Under normal conditions of use, there are no known hazardous reactions.

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.

Skin irritation: The components used in this product do not cause skin irritation.

Skin sensitization: The components used in this product do not cause skin sensitization.

Mutagenicity: The components used in the product do not show mutagenic effects on bacterial or mammalian cell cultures.

12. ECOLOGICAL INFORMATION

Environmental Overview: The substance is a synthetic biocompatible membrane and is not expected to produce toxic effects.

Aquatic Toxicity: The substance is a synthetic biocompatible membrane 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

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 classified as dangerous in the meaning of transport 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 Material 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