

# SAFETY DATA SHEET



## 1. PRODUCT AND COMPANY IDENTIFICATION

### Product Identifier

Material Name: Cytoflex® Tefguard® Ti-Enforced ePTFE Membrane  
Trade Name: Cytoflex® Tefguard® Ti-Enforced membrane  
Synonyms: Titanium reinforced 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  
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	%
Polytetrafluoroethylene	9002-84-0	Not listed	Not listed	~80
Titanium	7440-32-6	Not listed	Not listed	~20

### 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 CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

Hazardous thermal decomposition products: Acid fluorides, Fluorinated compounds, Hydrogen fluoride, Carbon monoxide

**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

**Color:** White

**Odor:** None

**Odor Threshold:** No data available

**Molecular Formula:** Not applicable. The substance is a titanium-containing PTFE membrane.

**Nominal formula Weight:** Not applicable

**pH:** No data available

**Water Solubility:** Not soluble

**Solvent Solubility:** No data available

**Melting/Freezing Point (°C):** 327-342

**Boiling Point (°C):** No data available

**Viscosity:** No data available

**Density:** Not applicable

**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 titanium-containing polymer and is not expected to produce toxic effects.

**Aquatic Toxicity:** The substance is a titanium-containing 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

**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