

The SDS format adheres to the standards and regulatory requirements of the United States and may not meet regulatory requirements in other countries.

Bioclear Matrix Systems Safety Data Sheet - TwinRings

"Delrin" Acetal Resin/PTFE Blends All In Synonem List DEL012 AND NiTi, Nickel Titanium,
Black-Ti® Wire

Revised September 14, 2023

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

1.1 Tradenames and Synonyms

"DELRIN" 100AF,

"DELRIN" 500AF, 510MP NC010, 520MP NC010,

"DELRIN" AFDE588,

"DELRIN" DE9266, DE9407, DE9410 NC010, DE9411 NC010,

"DELRIN" DE9413 NC010, DE9415 NC010,

"DELRIN" DE9432

NiTi, Nickel Titanium, Black-Ti[®] Wire

60% Glass Reinforced Poyamide Alloy

1.2 Company Identification

MANUFACTURER/DISTRIBUTOR

Bioclear Matrix Systems

By Dr David Clark

3802 South Warner Street, Suite A

Tacoma, WA 98409

USA

PHONE NUMBERS

Product Information 1-855-71-Clear (25327)

Transport Emergency CHEMTREC: 1-800-424-9300

SECTION 2: Hazards identification

Potential Health Effects





ADDITIONAL HEALTH EFFECTS

NITI

These products are not hazardous unless processed (i.e. ground, welded) in a manner that generates dust or fumes. Dust and fumes may cause eye, skin and respiratory irritation. May cause skin and respiratory tract sensitization (allergic reaction). Prolonged inhalation of dust or fumes from this product may cause perforation of the nasal septum and lung damage.

ACETAL POLYMER

There are no known effects from exposure to the Delrin polymer itself. If overheated, the polymer releases formaldehyde which may cause skin, eye, and respiratory irritation and allergic reactions.

Significant skin permeation and systemic toxicity after contact appears unlikely. There are inconclusive or unverified reports of human sensitization.

POLYTETRAFLUOROETHYLENE (PTFE)

Inhalation of PTFE dust may cause generalized irritation of the nose, throat and lungs with cough, difficulty breathing or shortness of breath.

Heating PTFE above 300 degrees C may liberate a fine particulate fume. Inhalation may produce polymer fume fever, a temporary flu-like condition with fever, chills, nausea, shortness of breath, chest tightness, muscle or joint ache, and sometimes cough and elevated white blood cell count. The symptoms are often delayed 4 to 24 hours after exposure. These signs are generally temporary, lasting 24-48 hours and resolve without further

complications. However, some individuals with repeated episodes of polymer fume fever have reported persistent pulmonary effects. Protection against polymer fume fever should also provide protection against any potential chronic effects.

Exposure to decomposition products from PTFE heated above 400 degrees C may cause pulmonary inflammation, hemorrhage or edema. These more serious consequences of exposure may occur from extreme





thermal decomposition of PTFE which can liberate fume particles, and toxic gases (carbonyl fluoride, hydrogen fluoride, and other fluorinated gases) especially under conditions of poor ventilation

and/or confined spaces. These decomposition products may initially produce chest tightness or pain, chills, fever, nausea, with shortness of breath, cough, wheezing and progression into pulmonary edema. Edema may be delayed in onset and requires medical treatment. In severe cases, if medical intervention is delayed, pulmonary edema may become life threatening. Recovery is generally complete within a few days; in some rare cases, persistent lung function abnormalities have been reported. Compared to nonsmokers, polymer fume fever symptoms appear to be more prevalent and serious in smokers. Smokers must avoid contamination of tobacco with residual polymer from their hands or from fumes, and should wash their hands before smoking.

Significant skin permeation, and systemic toxicity, after contact with the dust appears unlikely. There are no reports of human sensitization from contact with the dust.

If PTFE dusts contact the eye, mechanical irritation with tearing, pain or blurred vision may result.

Individuals with pre-existing diseases of the lungs or cardiovascular system may have increased susceptibility to the reduction in blood oxygen that may develop after excessive exposures to thermal decomposition products.

Carcinogenicity Information

The following components are listed by IARC, NTP, OSHA or ACGIH as

carcinogens.

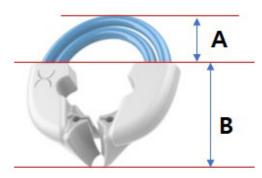
Material	IARC	NTP	OSHA	ACGIH
FORMALDEHYDE	1	X	X	A2





SECTION 3: Composition/information on ingredients

TwinRing Universal Composition:



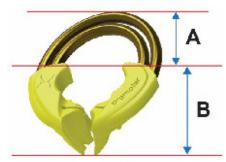
Part A Compostion:				
Material	CAS Number %			
Nickel	7440-02-0 / 231-111-4	45-60		
Titanium	7440-32-61231-142-3	40-50		

Part B Compostion:				
Material	CAS Number	%		
Polyamide (nylon) Resin Alloy	Proprietary Information	40		
Glass Fibers (for reinforcing)		60		





TwinRing Molar and TwinRing Premolar Composition:



Part A Compostion:				
Material	CAS Number %			
Nickel	7440-02-0 / 231-111-4	45-60		
Titanium	7440-32-6 231-142-3	40-50		

Part B Compostion:				
Material	CAS Number	%		
Acetal Polymer		>75		
Polytetrafluoroethylene	9002-84-0	<25		
Stabilizer		<4		
Formaldehyde	50-00-0	<0.005		

Components (Remarks)

Material is not known to contain Toxic Chemicals under Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR part 372. Additives in this product do not present a respiration hazard unless the product is ground to a powder of respirable size and the dust is inhaled. All dusts are potentially injurious to the respiratory tract if respirable particles are generated and inhaled in sufficiently high concentrations. Dust and fumes may cause eye, skin and respiratory irritation. May cause skin and respiratory tract sensitization (allergic reaction). Prolonged inhalation of dust or fumes from this product may cause perforation of the nasal septum and lung damage. Good industrial hygiene practices, as with all dusts, should include precautions to prevent inhalation of respirable particles.





SECTION 4: First aid measures

INHALATION

No specific intervention is indicated as the compound is not likely to be hazardous by inhalation. Consult a physician if necessary. If exposed to fumes from overheating or combustion, move to fresh air. Consult a physician if symptoms persist.

SKIN CONTACT

No first aid required for contact with solid product. The following information applies to contact from processing.

The compound is not likely to be hazardous by skin contact, but cleansing the skin after use is advisable. If molten polymer gets on skin, cool rapidly with cold water. Do not attempt to peel polymer from skin. Obtain medical treatment for thermal burn.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water, holding the eyelids apart to assure that the material is washed out, for at least 15 minutes. Call a physician if irritation persists.

INGESTION

No specific intervention is indicated as compound is not likely to be hazardous by ingestion. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

SECTION 5: Firefighting measures

5.1 Extinguishing media: Suitable extinguishing media – Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Further information: The product itself does not burn.

SECTION 6: Handling and storage

6.1 Conditions for safe storage, including any incompatibilities: Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Hygroscopic





SECTION 7: Stability and reactivity

- 7.1 Reactivity: No data available
- **7.2 Chemical stability:** Stable under recommended storage conditions.
- 7.3 Possibility of hazardous reactions: No data available
- **7.4 Conditions to avoid:** High temperature, fire.

SECTION 8: Toxicological information

- 8.1 Information on toxicological effects: No data available
- **8.2 Carcinogenicity:** IARC: No component of this product presented at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

SECTION 9: Transport information

9.1 Special precautions: Not Hazardous. Avoid transporting product in direct sunlight or high temperatures.

SECTION 10: Regulatory information

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

- **10.1** Safety, health and environmental regulations/legislation specific for the substance or mixture.: No data available
- **10.2 Chemical Safety Assessment:** For this product a chemical safety assessment was not carried out

SECTION 11: Other information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Bioclear Matrix Systems and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

End of MSDS

