

Bionate®

Thermoplastic Polycarbonate Polyurethane (PCU)



A proven family of highly biocompatible medical grade polymers with outstanding physical and mechanical properties

Bionate® PCU is an industry-leading medical grade polymer for use in long-term implants. It has been used in chronically implanted medical devices for nearly two decades. The Bionate® PCU family is one of the most extensively tested families of biomedical polymers and is backed by a comprehensive FDA Master File. Both Bionate® PCU and Bionate® II PCU are tough, biostable and biocompatible polymers with exceptional performance characteristics.

Widely Used

The Bionate® PCU family is currently being used in a wide range of applications, including neurostimulation, vascular, artificial heart, cardiac assist and diagnostic devices. Because of its exceptional load-bearing capability and biostability, it is also used extensively in orthopedic applications such as hip and knee joints and spinal motion preservation devices. Due to its biostability, flexibility, electrical properties and tensile strength, the Bionate® PCU family is an excellent candidate for lead insulation.

Tailor Made

Bionate® PCU can be modified with SME® technology to incorporate end groups that can enhance device performance. Bionate® II PCU also offers a wide range of potential surface characteristics by using DSM's patented SAME® technology.

Summary of Product Benefits

- **Biostable and biocompatible**
- **Extensively tested**
- **Backed by a comprehensive FDA Master File**
- **In use for nearly two decades**
- **Exceptional abrasion resistance, flexibility and tensile strength**
- **Adaptable with SME® and SAME® technology**

Bionate® PCU Physical Properties

Typical Property	Test Method	Bionate® PCU			
		80A	90A	55D	75D
Color	Visual			Clear to amber colored pellets	
Hardness, Durometer	ASTM D2240	83A	91A	56D	73D
Density, g/cm ³	ASTM D792	1.19	1.2	1.21	1.22
Ultimate Tensile Strength	ASTM D1708	6765 psi / 46.6 MPa	7993 psi / 55.1 MPa	8782 psi / 60.5 MPa	9171 psi / 63.2 MPa
Ultimate Elongation (%)	ASTM D1708	531	406	365	241
Tensile Stress					
at 50% elongation	ASTM D1708	634 psi / 4.4 MPa	1159 psi / 8.0 MPa	1772 psi / 12.2 MPa	5188 psi / 35.8 MPa
at 100% elongation		871 psi / 6.0 MPa	1604 psi / 11.1 MPa	2467 psi / 17.0 MPa	5825 psi / 40.2 MPa
at 300% elongation		2453 psi / 16.9 MPa	5345 psi / 36.9 MPa	6963 psi / 48.0 MPa	NA
Flexural Modulus, 1% Secant Modulus	ASTM D790	4160 psi / 28.7 MPa	6030 psi / 41.6 MPa	7000 psi / 48.3 MPa	260,000 psi / 1792.6 MPa
Flexural Stress, at 5% Deflection	ASTM D790	180 psi / 1.2 MPa	275 psi / 1.9 MPa	300 psi / 2.1 MPa	10,200 psi / 70.3 MPa
Tear Strength, Die 'C', pli	ASTM D624	370	550	780	1350
Coefficient of Linear Thermal Expansion					
x 10 ⁻⁶ /°C	ASTM E831	160.2	160.7	137.1	93.2
x 10 ⁻⁶ /°F	ASTM E1545	89	89.3	76.2	51.8
Water Absorption (%)	ASTM D750	1.2	NA	0.9	0.8
Dielectric Strength (V/mil)	ASTM D149	430	480	530	>625
Dielectric Constant, k', 60 hz	ASTM D150	5	4.8	4.5	3.7
Coefficient of Friction (Kinetic)	ASTM D1894	1.52	NA	0.81	0.64
Taber Abrasion, 1000g wt. Weight Loss, mg/1000 cycles	ASTM D1044 H-18 wheel	5.7	9.1	7.4	31
Vicat Softening Temp.					
°C	ASTM D1525	78	88	98	56
°F		173	190	208	133
Melt Flow Rate g/10 min at 224°C	ASTM D1238	(1200g) 22	(1200g) 14	(2160g) 20	(5000g) 14
Mold Shrinkage, % 4.0" Disk Flame Bar	ASTM D955	1.2 0-3.0	1.2 0-3.0	1.2 0.5-2.0	1.2 0.5-2.0
Recommended Extrusion Conditions					
°F		350-410	350-410	370-428	370-450
°C		180-210	180-210	190-220	190-232

Note: Typical physical property values are not to be construed as sales specifications.

Bionate® PCU Representative Biological Test Results

Biological test	Results	Biological test	Results
Ames Mutagenicity	Non-mutagenic	USP Pyrogenicity	Non-pyrogenic
Chronic Toxicity: USP Muscle Implantation	Macroscopic reaction not significant	Platelet Deposition (<i>ex vivo</i> shunt)	No difference in thrombogenicity when compared to ePTFE control
Complement Activation	Less activation of the complement system than ePTFE	Sensitization: Magnusson and Kligman	No dermal sensitization
USP Cytotoxicity (MEM Elution)	Non-cytotoxic	Acute Systemic Toxicity	No significant systemic toxicity
Humoral Immunological Study	No humoral (serological) immune response	USP Implantation Test: 7 days in rabbits	Macroscopic reaction not significant
Hemolysis	Non-hemolytic	Intracutaneous Toxicity	No significant irritation or toxicity
		Carcinogenicity: 2 years in rats	Non-carcinogenic

Bionate® II PCU Physical Properties

Typical Property	Test Method	Bionate® II PCU		
		80A	90A	55D
Color	Visual	clear to amber colored pellets		
Hardness, Durometer	ASTM D2240	84A	92A	56D
Ultimate Tensile Strength	ASTM D1708	7966 psi / 54.9 MPa	8615 psi / 59.4 MPa	8960 psi / 61.8 MPa
Ultimate Elongation (%)	ASTM 1708	501	385	372
Tensile Stress				
at 50% elongation	ASTM D1708	596 psi / 4.1 MPa	1358 psi / 9.4 MPa	1927 psi / 13.3 MPa
at 100% elongation		852 psi / 5.9 MPa	1909 psi / 13.2 MPa	2635 psi / 18.2 MPa
at 300% elongation		3504 psi / 24.2 MPa	6518 psi / 44.9 MPa	7105 psi / 49.0 MPa
Flexural Modulus, 1% Secant Modulus	ASTM D790	2780 psi / 19.2 MPa	6540 psi / 45.1 MPa	13800 psi / 95.1 MPa
Flexural Stress at 5% Deflection	ASTM D790	137 psi / 0.9 MPa	314 psi / 2.2 MPa	511 psi / 3.5 MPa
Water Absorption (%)	ASTM D750	0.74	0.72	0.54
Dielectric Strength (V/mil)	ASTM D149	425	423	420
Dielectric Constant, k', 60hz	ASTM D150	4.16	3.97	3.71
Coefficient of Friction (Kinetic)	ASTM D1894	0.41	0.43	0.46
Taber Abrasion, 1000gram wt. Weight Loss, mg/1000 cycles	ASTM D4060 H-18 wheel			11
Vicat Softening Temp.				
°C	ASTM D1525	82.5	94.7	106.9
°F		180.5	202.5	224.4
Melt Flow Rate g/10 min at 224°C	ASTM D1238	(1200g) 23	(1200g) 18	(2160g) 35
Glass Transition Temperature, Tg (°C)	ASTM E1356	-8	-2	1
Melting Point, Tm (°C)	ASTM E1356	162	177	180
Mold Shrinkage (%)	ASTM D955	.24-3.86	.83-2.71	.8-2.31
Recommended Extrusion Conditions				
°C			180 – 210	
°F			350 – 410	
Recommended Injection Molding Conditions				
°C			225 – 230	
°F			440 – 450	

Note: Typical physical property values are not to be construed as sales specifications.

Bionate® II PCU Representative Biological Test Results

Biological test	Results
Genotoxicity	Non-mutagenic
Hemocompatibility	Non-hemolytic
Cytotoxicity	Non-cytotoxic
Systemic Toxicity	No evidence of systemic toxicity
Irritation	No significant irritation or toxicity
Pyrogenicity	Non-pyrogenic
Sensitization	No evidence of sensitization; not considered a sensitizer
Implantation	Non-irritant

Data on file at DSM Biomedical Inc.
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