

Tough and Well-Known...

Industry leading material for industry changing devices

materials that belong to the body

Bionate® thermoplastic polycarbonate-urethane

a **DSM** Product

Bionate® thermoplastic polycarbonate-urethane (PCU) is an industry-leading medical grade polymer for use in long-term implants, and is backed by an established FDA Master File.

Bionate® PCU is an aromatic thermoplastic polycarbonate-urethane and has been used in chronically-implanted medical devices for nearly two decades. It has outstanding physical/mechanical properties with proven biostability and biocompatibility. DSM's surface modifying end group technology allows Bionate® PCU to be provided with customized surface characteristics to address device-specific requirements. It is currently used in a wide range of device applications including neurostimulation, cardiac assistance, and catheters. Bionate® PCU has also been used extensively in orthopedic applications, like hip and knee joints and prosthetic spinal discs for its outstanding load bearing qualities and biostability. It is an excellent candidate for lead insulation because of its abrasion resistance, flexibility and strength.

Proven Performer

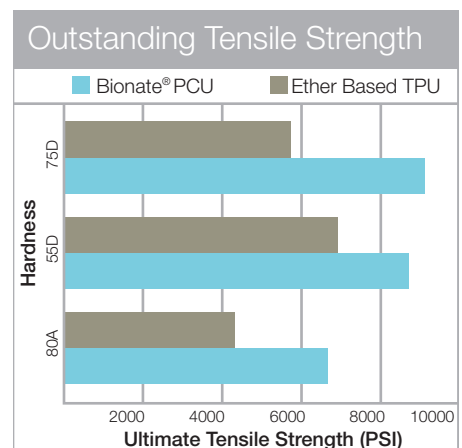
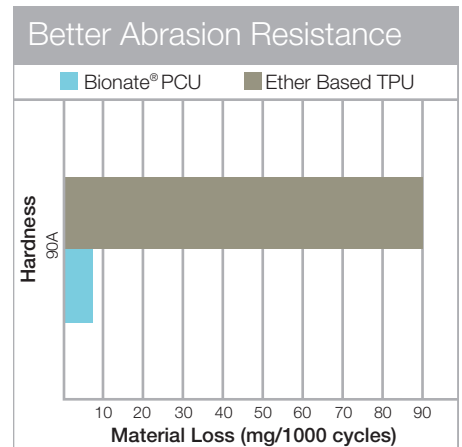
- Successfully used in approved medical devices for many years
- Comprehensive FDA Master File with carcinogenicity test results
- Outstanding abrasion resistance when compared to conventional silicone elastomers
- Higher strength than polyether urethanes

Biocompatible

- Improved resistance to environmental stress cracking (ESC), and significantly more stable against oxidation, particularly in the presence of metal ions such as cobalt (MIO)

Unique Surface Modifying Techniques

- Customizable with SME® technology, utilizing surface modifying end groups
- Surface modifying end groups give the polymer a choice of surface chemistry silicone, fluorocarbon, and polyethylene oxide
- Eliminates the need for additional surface processing steps after the device component is fabricated



Physical Properties

Typical Property	Test Method	Bionate® PCU				
		80A	90A	55D	65D	75D
Color	NA	Clear to amber colored pellets				
Hardness, Durometer	ASTM D2240	83A	91A	56D	66D	73D
Density, g/cm ³	ASTM D792	1.19	1.2	1.21	1.22	1.22
Tear Strength, Die 'C', pli	ASTM D624	370	550	780	NA	1350
Ultimate Tensile Strength (psi)	ASTM D1708	6765	7993	8782	9015	9171
Ultimate Elongation (%)	ASTM D1708	531	406	365	281	241
Tensile Stress at						
50% (psi)		634	1159	1772	3683	5188
100% (psi)	ASTM D1708	871	1604	2467	4601	5825
300% (psi)		2453	5345	6963	NA	NA
Flexural Modulus, psi 1% Secant Modulus	ASTM D790	4160	6030	7000	NA	260,000
Flexural Stress, psi at 5% Deflection	ASTM D790	180	275	300	NA	10,200
Water Absorption (%)	ASTM D750	1.2	NA	0.9	NA	0.8
Dielectric Strength (V/mil)	ASTM D149	430	480	530	NA	>625
Dielectric Constant, k', 60 hz	ASTM D150	5	4.8	4.5	NA	3.7
Coefficient of Friction (Kinetic)	ASTM D1894	1.52	NA	0.81	NA	0.64
Taber Abrasion, 1000g wt.	ASTM D1044					
Wear Index, mg/1000 cycles	H-18 wheel	5.7	9.1	7.4	NA	31
Vicat Softening Temp.						
°C	ASTM D1525	78	88	98	NA	56
°F		173	190	208		133
Coefficient of Linear Thermal Expansion						
x 10 ⁻⁶ /°C	ASTM E831	160.2	160.7	137.1	NA	93.2
x 10 ⁻⁶ /°F	ASTM E1545	89	89.3	76.2		51.8
Approximate Melt Index						
g/10 min at 224°C	ASTM D1238	(1200g)	(1200g)	(2160g)	(2160g)	(5000g)
		22	14	20	10	14
Mold Shrinkage, %						
4.0" Disk	ASTM D955	1.2	1.2	1.2	NA	1.2
Flame Bar		0-3.0	0-3.0	0.5-2.0		0.5-2.0
Optimum Extrusion Conditions						
°F		350-410	350-410	370-428	370-428	370-450
°C		180-210	180-210	190-220	190-220	190-232

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

Representative Biological Test Results

Biological test	Results
Ames Mutagenicity	Non-mutagenic
Chronic Toxicity: USP Muscle Implantation	Macroscopic reaction not significant
Complement Activation	Less activation of the complement system than ePTFE
USP Cytotoxicity (MEM Elution)	Non-cytotoxic
Humoral Immunological Study	No humoral (serological) immune response
Hemolysis	Non-hemolytic

Biological test	Results
USP Pyrogenicity	Non-pyrogenic
Platelet Deposition (ex vivo shunt)	No difference in thrombogenicity when compared to ePTFE control
Sensitization: Magnusson and Kligman	No dermal sensitization
Acute Systemic Toxicity	No significant systemic toxicity
USP Implantation Test: 7 days in rabbits	Macroscopic reaction not significant
Intracutaneous Toxicity	No significant irritation or toxicity
Carcinogenicity: 2 years in rats	Non-carcinogenic

Tests performed by and data on file at DSM PTG.

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DISCLAIMER

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