Chirulen® 1020-E Registered trademark of MediTECH Compression Molded Form

QUADRANT ENGINEERING PLASTIC PRODUCTS

Data Sheet MED-403-A5.0
Chirulen 1020-E
Rev 0 21JAN2014 2 pages

MediTECH® MEDICAL POLYMERS

Raw Material:Ticona GUR 1020 blended with 1000ppm wt% Alpha Tocopherol (Vitamin E) as an antioxidant

ISO Cell Designation: Thermoplast ISO 11542-PE-UHMW QD, 2-2-2

ASTM Cell Designation: S-UHMW-PE0111A111

***Medical Grade PE-UHMW with 1000ppm wt% Alpha-Tocopherol for surgical implants according to:**
ASTM F2695-12 and subsequently: ISO 5834-1-e2007,Type 1; ISO 5834-2-2006,Type 1; and ASTM F 648-13,Type 1

Characteristics of Base Resin: (Summarized from Ticona® C.O.C.'s)	Unit	ISO Standard	Pass Std	Avg Typ Values	ASTM Standard	Pass Std	Avg Typ Values
Titanium, trace element; maximum	[mg/kg]	5834-1	40	11	F 648	40	11
Aluminum, trace element; maximum	[mg/kg]	5834-1	20	3.5	F 648	20	3.5
Calcium, trace element; maximum	[mg/kg]	5834-1	5	3	F 648	5	3
Chlorine, trace element; maximum	[mg/kg]	5834-1	30	10	F 648	30	10
Extraneous Particles; maximum	[-]	5834-1	3	0-1	F 648	3	0-1
Glass Transition Temperature Tg	[^{o}C]	3146	na	-110	ISO 3146	na	-110
Crystallization Temp Range Tc (20-160^{o}C)	[^{o}C]	3146	na	134.5 - 142.5	ISO 3146	na	134.5 - 142.5
Oxidation Induction Time To, @ 200 ^{o}C	seconds	ASTM D3895	na	55.32	D 3895	na	55.32
Ash particles, Maximum	[mg/kg]	ISO 3451-1	125	45	ISO 3451-1	125	45
Average Particle Size (Typical)	[mm]	D50	≤16 Sieve	150	D50	≤16 Sieve	150
Avg. molecular wt [molar mass] according to: Data supplied by Ticona, converted from [IV]	[g/mol*10^{6}]	11534-1	na	5.166- 5.415	D 4020	na	3.121- 3.254
	[g/mol*10^{6}]	Margolies'	na	4.454 - 4.661			
Elongational stress Flow Value; F(150/10)	[MPa]	5834-1	≥0.2	0.23	D-4020	≥0.2	0.23
Viscosity Number [RSV]	[mL/g]	5834-1	2000-3200	2197 - 2276	D-4020	2000-3200	2197 - 2276
Porosity; (Bulk Density)	g/cm^{3}	DIN 53 479	na	.43 - .44	D 1895	na	.43 - .44
Crystallinity; DSC, (1st heat, 20C - 160C)	[%]	3146	na	66.89 - 70.23	D 3417	na	66.89 - 70.23

Conformances: Resin & Fabricated Forms; (Ticona Data)

Conformance		Records or Guidance
USP Class VI Biocompatability & ISO 10993 Cytotoxicity	Yes	Ticona Drug Master File -DMF 10904; USA Ticona Drug Master File -DMF 10916; EU Ticona Device Master File - MAF 588
ASTM F 648-13	Type 1	Powder and Fabricated Forms
ISO 5834-1, 2005	Type 1	Powder Form
ISO 5834-2, Fourth Edition, 01August 2011	Type 1	Fabricated Forms

Optional Processing Technology Available with MediTECH	*Industry Sterilization Methods	
Ram Extrusion of rounds and profiles	Ethylene Oxide [ETO]	Yes
Near-Net / Net Shape Molding	Gas Plasma	Yes
Additive / Antioxidant Blending	Gamma [Inert Atmosphere]	Yes
Gamma, E-Beam, X-Ray or Chemical Cross-Linking	Superheated Steam 121 °C	No
Inert Atmosphere Processing	Superheated Steam 134 °C	No
Specialized Fabrication: Pre-Forms, Fixturable Pucks	*These are not conducted by MediTECH	

MediTECH®, Quadrant Website & Location Addresses

MediTECH® - Quadrant USA; Fort Wayne, Indiana	MediTECH® - Quadrant France; Balan
MediTECH® - Quadrant Deutschland GmbH; Vreden	MediTECH® - Quadrant Japan; Tokyo
MediTECH® - Quadrant United Kingdom; Lancashire	MediTECH® - Quadrant China; Shanghai

For a complete list; locations, contacts, capabilities: Log onto www.meditechpolymers.com

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Characteristics of This Annealed, Fabricated Form	Unit	ISO Standard	Pass Std	Avg Typ Values	ASTM Standard	Pass Std	Avg Typ Values
Density, (Annealed Material)	[kg/m^3]	1183	927 - 944	937 / 1	D792/D1505	927-944	937 / 1
Tensile stress at yield [tensile strength]	[MPa]	527	≥21	22.2/0.2	D 638	≥21	22.8/0.4
Tensile stress at break [ultimate tensile strength]	[MPa]	527	≥35	59/5	D 638	≥40	68/4
Elongation Percent at break	[%]	527	≥300	460/15	D 638	≥380	470/15
Tensile (Young's) modulus; 2mm thick specimens:	[MPa]	527	na	683 / 28	D 638	na	490 / 37
Tensile Properties Conducted following: [ASTM Type IV @ 50 mm per minute and ISO Type 1B @ 100 mm per minute]							
Notched Impact Strength at 23 °C (Charpy, Izod)	[kJ/m^2]	11542-2	180	181/3	F 648	126	139/4
Shore hardness D-scale, 15 s value	[-]	868	≥60	66 / 2	D 2240	≥60	66 / 2
Poisson's Ratio (*Data supplied by Ticona)	[-]	5834-2	*0.46	*0.46	F 648	*0.46	*0.46
Crystallinity; DSC, (1st heat, 20C - 160C)	[%]	3146	na	≥ 54	F2625	na	≥ 54
Water absorption at 23 °C until saturation	[%]	62	<0.1	<0.05	D 570	<0.1	<0.05
Thermal Properties (Fabricated Form)							
Melting Point DSC, 10K/min	[°C]	3146	na	137.1/0.2	F2625	na	137.1/0.2
Vicat softening point, 10N, 50 C°/Hr	[°C]	306	na	134	D 1525 B	na	134
Coef. of Linear thermal expansion; 23 °C to 80 °C	K^{-1}	11359	na	1.8*10-4	D 696	na	1.8*10-4
Heat Deflection T: HDT/A [1.8 MPa] 66psi/264psi	[°C]	75 pt 1/2	na	[42]	D 648	na	80 / 46
Thermal Conductivity	[W/(m*K)]	DIN 52612	na	approx. 0.4	DIN 52612	na	approx 0.4
Glass Transition Temperature Tg	[°C]	DSC	na	-110	DSC	na	-110
Crystallization Temperature Range Tc (20-160°C)	[°C]	DSC	na	126.21 - 143.54	DSC	na	126.21-143.54
Oxidation Induction Time To, conducted @ 200 °C	Minutes	D 3895	na	Results Available April 2014	D 3895	na	Results Available April 2014
Ash particles, maximum	[mg/kg]	ISO 3451 -1	150	60 - 90	ISO 3451-1	150	60 - 90

Oxidation Resistance Test Results: (ASTM F2101-01 AND ISO 5834-4; 2005);
Shelf aged 1 Year in Air Results: Surface Oxidation Index **0.0**; Bulk Oxidation Index **0.0**

Accelerated Aged 2 wks & 4wks according to: (ASTM F 2003 and ISO 5834-3); and Oxidative Index Measured by: (ASTM F2101-01) Oxidation Index **0.0**; Bulk Oxidation Index **0.0**

Regulatory Submission Support Available through MediTECH for Enhanced Forms

Produce Materials to customer specifications; Characterize and report according to validation protocols as evidence for new product development and submission according to:

ASTM F 2565-13; "Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricaed Forms for Surgical Implant Applications[1]"

ASTM F 2695-12; "Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended with Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications[1]"

ASTM F 2759; "Standard Guide for Assessment of the Ultra High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices[1]"

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IMPORTANT: Most plastics will ignite and sustain flame under certain conditions. Caution is urged where any material may be exposed to open flame or heat-generating equipment. Use Material Safety Data Sheets to determine auto-ignition and flashpoint temperatures of materials, or consult MediTECH if additional information is needed.