

Chirulen[®] 1050- Registered trademark of MediTECH Compression Molded Form



Data Sheet MED-403-A3.0
Chirulen 1050
Rev 0 21Jan2014 2 pages



Raw Material: Ticona GUR 1050

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

ASTM Cell Designation: S-UHMW-PE0111A111

*Medical Grade PE-UHMW for surgical implants according to:
ISO 5834-1-e2007, Type 2; ISO 5834-2-2006, Type 2; and ASTM F 648-13, Type 2

<u>Characteristics of Base Resin: (Summarized from Ticona® C.O.C.'s)</u>	Unit	ISO Standard	Pass Std	Avg Typ Values	ASTM Standard	Pass Std	Avg Typ Values
Titanium, trace element; maximum	[mg/kg]	5834-1	≤40	10.6	F 648	≤40	10.6
Aluminum, trace element; maximum	[mg/kg]	5834-1	≤20	3.3	F 648	≤20	3.3
Calcium, trace element; maximum	[mg/kg]	5834-1	≤5	2	F 648	≤5	2
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 T _g	[°C]	3146	na	-110	ISO 3146	na	-110
Crystallization Temp Range T _c (20-160°C)	[°C]	3146	na	134.5 - 142.5	ISO 3146	na	134.5 - 142.5
Oxidation Induction Time T _o , @ 200 °C	seconds	ASTM D3895	na	55.32	D 3895	na	55.32
Ash particles, Maximum	[mg/kg]	ISO 3451-1	125	38	ISO 3451-1	125	38
Average Particle Size (Typical)	[mm]	D50	≤#16 Sieve	152	D50	≤#16 Sieve	152
Avg. molecular wt [molar mass] according to: Data supplied by Ticona, converted from [IV]	[g/mol*10 ⁶]	11534-1	na	9.749 to 10.266	D 4020	na	5.490 to 5.748
	[g/mol*10 ⁶]	Margolies'	na	8.234 to 8.656			
Elongational stress Flow Value; F(150/10)	[MPa]	5834-1	≥0.42	0.49	D-4020	≥0.42	0.49
Viscosity Number [RSV]	[mL/g]	5834-1	>3200	3532 to 3677	D-4020	>3200	3532 to 3677
Porosity; (Bulk Density)	g/cm ³	DIN 53 479	na	.43 to .44	D 1895	na	.43 to .44
Crystallinity; DSC, (1st heat, 20C - 160C)	[%]	3146	na	49 - 58	F2625	na	49 - 58

Conformances: Resin & Fabricated Forms; (Ticona Data)

Conformance	Records or Guidance
USP Class VI Biocompatibility & 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 2 Powder and Fabricated Forms
ISO 5834-1, 2005	Type 2 Powder Form
ISO 5834-2, Fourth Edition, 01August 2011	Type 2 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	Typical Values / Stdev	ASTM Standard	Pass Std	Typical Values / Stdev
Density, (Annealed Material)	[kg/m ³]	1183	927 - 944	932 / 1	D792/D1505	927 - 944	932 / 1
Tensile stress at yield [tensile strength]	[MPa]	527	≥19	21.5/0.8	D 638	≥19	21.4/0.5
Tensile stress at break [ultimate tensile strength]	[MPa]	527	≥27	53.5/4	D 638	≥40	59.6/2
Elongation Percent at break	[%]	527	≥300	380/15	D 638	≥340	400/15
Tensile (Young's) modulus; 2mm thick specimens:	[MPa]	527	na	660 / 37	D 638	na	618 / 26
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	90	91/2	F 648	73	95/4
Shore hardness D-scale, 15 s value	[-]	868	≥60	67 / 1	D 2240	≥60	67 / 1
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	>52	F2625	na	>52
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	F2625	na	137
Vicat softening point, 10N, 50 C°/Hr	[°C]	306	na	135	D 1525 B	na	135
Coef. of Linear thermal expansion; 23 °C to 80 °C	K ⁻¹	11359	na	2.2*10 ⁻⁴	D 696	na	2.2*10 ⁻⁴
Heat Deflection T: HDT/A [1.8 MPa] 66psi/264psi	[°C]	75 pt 1/2	na	[45]	D 648	na	[45]
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 (50-160°C)	[°C]	DSC	na	128.72 - 144.10	DSC	na	128.72 - 144.10
Oxidation Induction Time To, conducted @ 200 °C	minutes	D 3895	na		D 3895	na	
Ash particles, maximum	[mg/kg]	ISO 3451 -1	150	80	ISO 3451-1	125	80

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**

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 Fabricated Forms for Surgical Implant Applications"¹ⁿ

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"¹ⁿ

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

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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.