PRODUCT DATA SHEET

Chirulen ® 1020E HXLPE

75 kGy 150°C Post Gamma Anneal

MediTECH Compression Molded and Irradiated UHMWPE Form, produced from Celanese GUR 1020E resin. Chirulen® 1020E, 75 kGy, Above Melt Annealed materials maintain the toughness of UHMWPE, while providing the enhanced wear properties of the more highly crosslinked polymer, with the stability provided by the above melt annealing for free radical neutralization.

ISO Cell Designation: Thermoplastic ISO 11542-PE-UHMW QD, 2-2-2, ASTM Cell Designation: S-UHMW-PE0111A111

Material evaluated based on ISO 5834-1 Type 1, ISO 5834-2 Type 1, and ASTM F648 Type 1. Note - ISO 5834-2:2019 has updated to ASTM test methods, but for the purposes of comparison to previous testing the ISO test methods of the previous ISO 5834-2 standards have been included.

	ISO 5834-2:2011			ISO 5834-2:2019 and ASTM F648:2014		
Annealed Fabricated Form Prior to Crosslinking	**Test methods**	**Units**	**Indicative Values**	**Test methods**	**Units**	**Indicative Values**
Mechanical Properties (Note 2)						
Density, (Annealed Material)	ISO 1183	[kg/m3]	935 (2)	ASTM D792 / ASTM D1505	[kg/m3]	935 (2)
Tensile stress at yield [tensile strength]	ISO 5834-2 / ISO 527	[MPa]	22.5 (0.9)	ASTM F648 / ASTM D638	[MPa]	21.7 (0.6)
Tensile stress at break [ultimate tensile strength]	ISO 5834-2 / ISO 527	[MPa]	61.8 (6)	ASTM F648 / ASTM D638	[MPa]	57.6 (5)
Elongation Percent at break	ISO 5834-2 / ISO 527	[%]	454 (12)	ASTM F648 / ASTM D638	[%]	450 (15)
Shore Hardness D-Scale, 15 sec. value	ISO 868	[-]	66 (2)	ASTM D2240	[-]	66 (2)
Notched Impact Strength (Charpy, Izod)	ISO 11542-2	[kJ/m2]	196 (4)	ASTM F648	[kJ/m2]	144 (9)
Crystallinity; DSC, (1st heat, 20°C - 160°C)	N / A	N / A	N / A	ASTM F2625	[%]	59 (3)
Water absorption at 23 °C until saturation	ISO 62	%	<0.05	ASTM D570	[%]	<0.05
Thermal Properties						
Melting temperature (DSC, 10°C / min)	N / A	N / A	N / A	ASTM DF2625	°C	136 (0.9)
Vicat softening point, 10N, 50 °C/Hr.	ISO 306	[°C]	134	ASTM D1525 B	[°C]	134
Coef. of Linear thermal expansion; 23°C to 80°C	ISO 11359	[K^{-1}]	1.8*10-4	ASTM D696	[K^{-1}]	1.8*10-4
Heat Deflection T: HDT/A [1.8 MPa]; 264psi	ISO 75 pt. 1/2	[°C]	42	ASTM D648	[°C]	42
Thermal Conductivity	DIN 52612	[W/(m*K)]	Approx. 0.4	DIN 52612	[W/(m*K)]	Approx. 0.4
Crystallization Temperature Range Tc; (20-160°C)	ISO 3146	[°C]	126 - 144	ASTM F2625	[°C]	126 - 144
Ash particles, maximum	ISO 3451 -1	[mg/kg]	≤150	N / A	N / A	N / A
Oxidation Resistance - Surface Oxidation Index	ISO 5834-4	Index	≤0.1	ASTM F2102	Index	≤0.1
Oxidation Resistance - Bulk Oxidation Index	ISO 5834-4	Index	≤0.1	ASTM F2102	Index	≤0.1
Oxidation Induction Time T_0, conducted @ 200°C	N / A	N / A	N / A	ASTM D3895	Minutes	50-55
Crosslinked Fabricated Form	**Test methods**	**Units**	**Indicative Values**	**Test methods**	**Units**	**Indicative Values**
Mechanical Properties (Notes 1, 2)						
Density, (Annealed Material)	ISO 1183	[kg/m3]	932 (1.3)	ASTM D792 / ASTM D1505	[kg/m3]	932 (1.3)
Tensile stress at yield [tensile strength]	ISO 5834-2 / ISO 527	[MPa]	22 (0.4)	ASTM F648 / ASTM D638	[MPa]	21.7 (0.5)
Tensile stress at break [ultimate tensile strength]	ISO 5834-2 / ISO 527	[MPa]	50 (2)	ASTM F648 / ASTM D638	[MPa]	48.4 (2.7)
Elongation Percent at break	ISO 5834-2 / ISO 527	[%]	350 (15)	ASTM F648 / ASTM D638	[%]	368 (10)
Notched Impact Strength (Charpy, Izod)	ISO 11542-2	[kJ/m2]	80 (2)	ASTM F648	[kJ/m2]	89 (1.7)
Crystallinity; DSC, (1st heat, 20°C - 160°C)	N / A	N / A	N / A	ASTM F2625	[%]	51.8 (2.7)
Water absorption at 23 °C until saturation	ISO 62	[%]	< 0.05	ASTM D570	[%]	< 0.05
Compressive Modulus	N / A	N / A	N / A	ASTM D792	[MPa]	655 (32)
Thermal Properties (Note 1)						
Melting temperature (DSC, 10°C / min)	N / A	N / A	N / A	ASTM DF2625	[°C]	134.0 (0.7)
Ash particles, maximum	ISO 3451 -1	[mg/kg]	≤150	N / A	N / A	N / A
Oxidation Resistance - Surface Oxidation Index	ISO 5834-4	Index	≤0.1	ASTM F2102	Index	≤0.1
Oxidation Resistance - Bulk Oxidation Index	ISO 5834-4	Index	≤0.1	ASTM F2102	Index	≤0.1

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MediTECH MEDICAL POLYMERS

MITSUBISHI CHEMICAL ADVANCED MATERIALS

Crosslinked Fabricated Form	ISO*			ASTM*		
	Test methods	Units	Indicative Values	Test methods	Units	Indicative Values
Small Punch Properties (Notes 1, 2)						
Nominal Yield	N / A	N / A	N / A	ASTM F2183	N	69.2 (5.5)
Maximum Load	N / A	N / A	N / A	ASTM F2183	N	88.2 (9)
Maximum Displacement	N / A	N / A	N / A	ASTM F2183	mm	4.8 (0.2)
Work to Failure	N / A	N / A	N / A	ASTM F2183	mJ	273 (23)
Fatigue Crack Propagation Properties (Note 1)						
C (Y Intercept) Linear Region	N / A	N / A	N / A	Per CPG Procedure	mm/cycle	1.02E-08 (5.09E-09)
C (Y Intercept) 1x10-7 to 2x10-4	N / A	N / A	N / A	Per CPG Procedure	[m/cycle/(Mpa*m^1/2)^m)]	N/A
m (exponent) Linear Region	N / A	N / A	N / A	Per CPG Procedure	for ΔK in MPa*m^1/2	6.401 (0.28)
m (exponent) 1x10-7 to 2x10-4	N / A	N / A	N / A	Per CPG Procedure	for ΔK in MPa*m^1/2	N/A
ΔK inception	N / A	N / A	N / A	Per CPG Procedure	MPa*m^1/2	1.502 (0.17)
Oxidation Properties (Notes 1, 3, 4)						
Surface Oxidative Index, Time = 0	N / A	N / A	N / A	ASTM F2102	Index	< 0.1
Bulk Oxidative Index, Time = 0	N / A	N / A	N / A	ASTM F2102	Index	< 0.1
Maximum Oxidative Index, Time = 0	N / A	N / A	N / A	ASTM F2102	Index	N/A
Surface Oxidative Index, Time = 2 weeks	N / A	N / A	N / A	ASTM F2102 / ASTM F2003	Index	0.1
Bulk Oxidative Index, Time = 2 weeks	N / A	N / A	N / A	ASTM F2102 / ASTM F2003	Index	0.1
Maximum Oxidative Index, Time = 2 weeks	N / A	N / A	N / A	ASTM F2102 / ASTM F2003	Index	N/A
Determination of Network Parameters of Crosslinking (Note 1)						
In Situ Swell Ratio	N / A	N / A	N / A	ASTM F2214	Ratio	3.82 (0.1)
In Situ Crosslink Density	N / A	N / A	N / A	ASTM F2214	mol/dm^3	0.13 (0.005)
In Situ Molecular Weight between Crosslinks	N / A	N / A	N / A	ASTM F2214	g/mol	6894.1 (311)
Trans Vinylene Yield by Infrared Spectroscopy for Cross Link Density	N / A	N / A	N / A	ASTM F2381	Ratio	0.023
Electron Spin Resonance	N / A	N / A	N / A	N / A	Spins / gram	-5.081E+13 (5.56E+13)

NOTES, SEE DATASHEET ON PAGE 1 AND 2

Note 1 All of the values / ranges for the Cross-Linked Fabricated Forms represent typical values / ranges for the product being produced. Standard deviations, where available, are presented within parentheses. These values are not listed in a standard, nor required by a regulatory body. The Applicable Test Standards designate the test types only, but there are no values in the standards for Cross-Linked materials. These values will vary significantly based on the cross-link dose and the Post-Irradiation Anneal chosen. MediTECH has no such criteria either as the requirements may be application dependent. This information may be used for comparative work used in regulatory submissions, especially regarding predicate devices, in design exercises, or for the purposes of failure analysis for review of a material. However, they are not guaranteed and they should not be used to establish material specification limits nor used alone as the basis of design.

Note 2 Tensile Properties Conducted following: [ASTM Type IV @ 50 mm per minute and ISO Type 1B @ 100 mm per minute]

Note 3 Accelerated Aging may be performed for various time periods. A period of two weeks has been selected to provide a time period for consistent testing

Note 4 Oxidative Indices: The process used can affect the oxidative potential. In the development of a material the goal is always to have "essentially zero" oxidative potential, that is typically numerically determined to be an index of 0.1 or less.

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GENERAL NOTES

This product data sheet and any data and specifications presented on our website shall provide promotional and general information about the Engineering Plastic Products (the "Products") manufactured and offered by Mitsubishi Chemical Advanced Materials Inc. and shall serve as a preliminary guide. All data and descriptions relating to the Products are of an indicative nature only. Neither this data sheet nor any data and specifications presented on our website shall create or be implied to create any legal or contractual obligation.

Any illustration of the possible fields of application of the Products shall merely demonstrate the potential of these Products, but any such description does not constitute any kind of covenant whatsoever. Irrespective of any tests that Mitsubishi Chemical Advanced Materials Inc. may have carried out with respect to any Product, Mitsubishi Chemical Advanced Materials Inc. does not possess expertise in evaluating the suitability of its materials or Products for use in specific applications or products manufactured or offered by the customer respectively. The choice of the most suitable plastics material depends on available performance data and practical experience, but often preliminary testing of the finished plastics part under actual service conditions (right physical, mechanical, temperature and contact time, as well as other conditions) is required to assess its final suitability for the given application.

It thus remains the customer's sole responsibility to test and assess the suitability and compatibility of the products of Mitsubishi Chemical Advanced Materials Inc. for its intended applications, processes and uses, and to choose those Products which according to its assessment meet the requirements applicable to the specific use of the finished product. The customer undertakes all liability in respect of the application, processing or use of the aforementioned information or product, or any consequence thereof, and shall verify its quality and other properties.

Regulatory Submission Support Available through MediTECH for Enhanced Forms

Mitsubishi Chemical Advanced Materials Inc. is able to produce Materials to customer specifications, characterize and report as requested 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[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 2759-19; "Standard Guide for Assessment of the Ultra High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices[1]"

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.

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