

Ketron® CLASSIX™ LSG PEEK white stock shapes are produced from Invibio® PEEK-CLASSIX™ White resin. This material exhibits a unique combination of mechanical properties, temperature and chemical resistance. The composition of the Invibio PEEK-CLASSIX[™] White resin complies with the regulations that apply in the Member States of the European Union (Directive 2002/72/EC, as amended) and in the United States of America (FDA) for plastic materials and articles intended to come into contact with foodstuffs. Ketron® CLASSIXTM LSG PEEK stock shapes have also been successfully type tested for their compliance with both United States Pharmacopeia (USP) and ISO 10993-1 guideline requirements for Biocompatibility Testing of Materials, and they come with full traceability from resin to stock shape. These features, added to an excellent sterilizability by means of steam, dry heat, ethylene oxide, plasma and gamma irradiation, make Ketron® CLASSIXTM LSG PEEK stock shapes very suitable for applications in the medical, pharmaceutical and biotechnology markets.

Physical properties (indicative values *)

ROPERTIES	Test methods	Units	VALUES
Colour	-	-	White
Density	ISO 1183-1	g/cm ³	1.39
Vater absorption:			
- after 24h immersion in water of 23 °C (1)	ISO 62	%	
- at saturation in water of 23 °C	-	%	0.45
Thermal Properties (2)			
Melting temperature (DSC, 10 °C/min)	ISO 11357-1/-3	°C	340
Glass transition temperature (DSC, 20 °C/min) - (3)	ISO 11357-1/-2	°C	
Thermal conductivity at 23 °C		W/(K.m)	0.25
Coefficient of linear thermal expansion:		. ()	
- average value between 23 and 100 °C	-	m/(m.K)	-
- average value between 23 and 150 °C		m/(m.K)	-
- average value above 150 °C	_	m/(m.K)	-
Temperature of deflection under load:		- 1, 1	
- method A: 1.8 MPa	ISO 75-1/-2	°C	165
Max. allowable service temperature in air:			
- continuously : for min. 20,000 h (4)	_	°C	250
Min. service temperature (5)		°C	-50
Flammability (6):			
- according to UL 94 (3 mm thickness)	_	-	V-0
Mechanical Properties at 23 °C (7)			
Tension test (8):			
- tensile strength (9)	ISO 527-1/-2	MPa	115
- tensile strain at yield(9)	ISO 527-1/-2	%	
- tensile strain at break (9)	ISO 527-1/-2	%	14
- tensile modulus of elasticity (10)	ISO 527-1/-2	MPa	4600
Compression test (11):			
- compressive stress at 1 / 2 / 5 % nominal strain (10)	ISO 604	MPa	40 / 79 / 143
Flexural test (12):			
- flexural strength	ISO 178	MPa	-
- flexural modulus of elasticity	ISO 178	MPa	
Charpy impact strength - unnotched (13)	ISO 179-1/1eU	kJ/m²	400
Charpy impact strength - notched	ISO 179-1/1eA	kJ/m²	3.5
Rockwell M-hardness (14)	ISO 2039-2	-	105
Dynamic Coefficient of Friction (-)	ISO 7148-2 (15)	-	0.3-0.5
Wear rate	ISO 7148-2 (15)	μm/km	28
Electrical Properties at 23 °C	(13)		
Electric strength (16)	IEC 60243-1	kV/mm	
Volume resistivity	IEC 60093	Ohm.cm	>10E 14
Surface resistivity	ANSI/ESD STM 11.11	Ohm/sq.	>10E13
Relative permittivity ε _r : - at 1 MHz	IEC 60250	-	
Dielectric dissipation factor tan δ: - at 1 MHz	IEC 60250	-	
ertifications on biocompatibility type testing	.20 00200		

According to method 1 of ISO 62 and done on discs \varnothing 50 mm x 3 mm.

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- 2)
- The figures given for these properties are for the most part derived from raw material supplier data and other publications. Values for this property are only given here for amorphous materials and for materials that do not show a melting temperature (PBI, PAI, PI). Temperature resistance over a period of min. 20,000 hours. After this period of time, there is a decrease in tensile strength measured at 23 °C of about 50 % as compared with the original value. The temperature value given here is thus based on the thermal-oxidative degradation which takes place and causes a reduction in properties. Note, however, that the maximum allowable service temperature depends in many cases essentially on the duration and the magnitude of the mechanical on the duration and the magnitude of the mechanical
- on the duration and the magnitude of the mechanical stresses to which the material is subjected. Impact strength decreasing with decreasing temperature, the minimum allowable service temperature is practically mainly determined by the extent to which the material is subjected to impact. The value given here is based on unfavourable impact conditions and may consequently not be considered as being the absolute practical limit. These estimated ratings, derived from raw material supplier data and other publications, are not intended to reflect heardris presented by the material under actual.
- reflect hazards presented by the material under actual fire conditions. There is no 'UL File Number' available for
- fire conditions. There is no 'UL File Number' available for these stock shapes.

 Most of the figures given for these mechanical properties of the materials are average values of tests run on dry test specimens machined either out of plate 15-20 mm thick or rod diameter 40-50mm, the test specimens were then taken from the stock shape with their length in longitudinal direction (parallel to the extrusion direction). Test specimens: Type 1 B

 Test specimens: Type 1 B

 Test speed: either 5 or 50 mm/min [chosen acc. to ISO 10350.1 as a function of the ductile behaviour of the
- Test specimens: bars 4 mm (thickness) x 10 mm x 80

- Test specimens: Dars 4 min (thickness) x 10 min x 80 min; test speed: 2 mm/min; span: 64 min. Pendulum used: 4 J. Measured on 10 mm thick test specimens. Test procedure similar to Test Method A: "Pin-on-disk" as described in ISO 7148-2, Load 3MPa, sliding velocity= 0,33 m/s, mating plate steel Ra= 0.7-0.9 µm, tested at 23°C, 50%RH.
- Electrode configuration: Ø 25 mm / Ø 75 mm coaxial cylinders; in transformer oil according to IEC 60296; 1 mm thick test specimens.

This table is a valuable help in the choice of a material. The data listed here fall within the normal range of product properties of <u>dry</u> 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.

It has to be noted that reinforced and filled material shows an anisotropic behaviour (properties differ when measured parallel and perpendicular to the manufacturing direction).

Note: 1 g/cm³ = 1,000 kg/m³; 1 MPa = 1 N/mm²; 1 kV/mm = 1 MV/m.

Mitsubishi Chemical Advanced Materials Life Science Grades should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours/30 days*, or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours/30 days*, or as critical components of medical devices that are essential to the continuation of human life

*: the period of 30 days only applies to Ketron® CLASSIX™ LSG PEEK white

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PEEK-CLASSIX[™] is a trademark of Invibio Ltd.

ISO 10993-11 (acute systemic toxicity)

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