Covestro Makrolon® 3258 Polycarbonate, General Purpose, Mold Release, Biocompatibility

Category : Polymer , Thermoplastic , Polycarbonate (PC) , Polycarbonate, Molded

Material Notes:

It is the responsibility of the medical device, biological product, or pharmaceutical manufacturer (Manufacturer) to determine the suitability of all component parts and raw materials, including the Bayer Corporation product identified in this electronic database, used in its final product in order to ensure safety and compliance with FDA regulations. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of solutions/liquids, including, without limitation, blood, medication, or other bodily fluids. Under no circumstances, however, may the Bayer Corporation product be used in any cosmetic, reconstructive or reproductive implant applications. Nor may any Bayer Corporation resin be used in any other bodily implant applications or any applications involving contact with or storage of human tissue, blood or other bodily fluids for greater than 30 days, based on FDA modified ISO 10993, Part 1 Biological Evaluation of Medical Devices tests. Furthermore, for aromatic grades of Texin TPU resins, longer term uses are not permissible because possible hydrolysis of solid urethane may produce aromatic amines, such as methylene dianiline (MDA). The suitability of a Bayer product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stress, or external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof. Single use medical devices made from Bayer products are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof. If you have any questions on the regulatory status of any of Bayer Corporation products identified in this electronic database, please contact your local Bayer Corporation representative or the Bayer Corporation Regulatory Affairs Manager in the Health, Environment, and Safety Department in Pittsburgh, Pa. Biocompatibility Information The medical grades of the Bayer Corporation products identified in this electronic database have met the FDA modified ISO 10993, Part 1 Biological Evaluation of Medical Devices tests with human tissue contact time of 30 days or less. ONLY THESE PRODUCTS MAY BE CONSIDERED AS CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY. No medical grade products will be available for sale until successful completion of testing. Regrind resins must not be used in medical applications requiring biocompatibility. Sterilization Information The sterilization method and the number of sterilization cycles a part made from a Bayer Corporation product identified in this electronic database can withstand will vary depending upon the type and grade of resin, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the Manufacturer must evaluate each device to deterAs of 1 September 2015, Bayer MaterialScience was separated from Bayer AG and officially adopted its new name – Covestro.

Order this product through the following link:
http://www.lookpolymers.com/polymer_Covestro-Makrolon-3258-Polycarbonate-General-Purpose-Mold-Release-Biocompatibility.php

Physical Properties	Metric	English	Comments
Density	1.20 g/cc	0.0434 lb/in³	ASTM D792
Water Absorption	0.15 %	0.15 %	24 hour immersion; ASTM D570
Water Absorption at Saturation	0.35 %	0.35 %	Equilibrium Immersion; ASTM D570

Physical Properties	Metric	English	Comments
Linear Mold Shrinkage	0.0060 - 0.0080 cm/cm	0.0060 - 0.0080 in/in	ASTM D955
Melt Flow	4.5 g/10 min @Load 1.20 kg, Temperature 300 °C	4.5 g/10 min @Load 2.65 lb, Temperature 572 °F	ASTM D1238

Mechanical Properties	Metric	English	Comments
Hardness, Rockwell M	75	75	ASTM D785
Hardness, Rockwell R	118	118	ASTM D785
Tensile Strength, Ultimate	72.0 MPa	10400 psi	ASTM D638
Tensile Strength, Yield	63.0 MPa	9140 psi	ASTM D638
Elongation at Break	125 %	125 %	ASTM D638
Elongation at Yield	6.0 %	6.0 %	ASTM D638
Tensile Modulus	2.40 GPa	348 ksi	ASTM D638
Flexural Yield Strength	86.0 MPa	12500 psi	at 5% strain; ASTM D790
Flexural Modulus	2.28 GPa	331 ksi	ASTM D790
Izod Impact, Notched	9.60 J/cm @Thickness 3.17 mm	18.0 ft-lb/in @Thickness 0.125 in	ASTM D256

Thermal Properties	Metric	English	Comments
CTE, linear	70.0 µm/m-°C @Temperature 20.0 °C	38.9 µin/in-°F @Temperature 68.0 °F	ASTM D696
Specific Heat Capacity	1.20 J/g-°C	0.287 BTU/lb-°F	ASTM D2766
Thermal Conductivity	0.200 W/m-K	1.39 BTU-in/hr-ft²-°F	ASTM C177
Deflection Temperature at 0.46 MPa (66 psi)	142 °C	288 °F	Unannealed; ASTM D648
Deflection Temperature at 1.8 MPa (264 psi)	132 °C	270 °F	Unannealed; ASTM D648
Vicat Softening Point	157 °C	315 °F	Rate A; ASTM D1525
UL RTI, Electrical	125 °C @Thickness 1.50 mm	257 °F @Thickness 0.0591 in	UL746B
UL RTI, Mechanical with Impact	115 °C @Thickness 1.50 mm	239 °F @Thickness 0.0591 in	UL746B

Thermal Properties	Metric	English	Comments
UL RTI, Mechanical without Impact	125 °C @Thickness 1.50 mm	257 °F @Thickness 0.0591 in	UL 746B
Flammability, UL94	HB @Thickness 1.50 mm	HB @Thickness 0.0591 in	
	HB @Thickness 1.50 mm	HB @Thickness 0.0591 in	
Oxygen Index	26 %	26 %	ASTM D2863

Optical Properties	Metric	English	Comments
Refractive Index	1.586	1.586	ASTM D542
Haze	1.0 % @Thickness 3.17 mm	1.0 % @Thickness 0.125 in	ASTM D1003
Transmission, Visible	88 % @Thickness 3.20 mm	88 % @Thickness 0.126 in	ASTM D1003

Electrical Properties	Metric	English	Comments
Electrical Resistivity	1.00e+16 ohm-cm	1.00e+16 ohm-cm	ASTM D257
Surface Resistance	1.00e+15 ohm	1.00e+15 ohm	ASTM D257
Dielectric Constant	2.9 @Frequency 1e+6 Hz	2.9 @Frequency 1e+6 Hz	ASTM D150
	3.0 @Frequency 60 Hz	3.0 @Frequency 60 Hz	ASTM D150
Dielectric Strength	30.0 kV/mm @Thickness 1.60 mm	762 kV/in @Thickness 0.0630 in	ASTM D149
Dissipation Factor	0.00090 @Frequency 60 Hz	0.00090 @Frequency 60 Hz	ASTM D150
	0.010 @Frequency 1e+6 Hz	0.010 @Frequency 1e+6 Hz	ASTM D150
Arc Resistance	120 sec	120 sec	Tungsten Electrodes; ASTM D495
Comparative Tracking Index	>= 600 V @Thickness 3.00 mm	>= 600 V @Thickness 0.118 in	UL Rating PLC 0 (>600 V)

Electrical Properties	Metric	English	Comments
	30 - 60 sec @Thickness 3.00 mm	30 - 60 sec @Thickness 0.118 in	UL Rating PLC 2 (30-60 sec)
High Amp Arc Ignition, HAI	>= 120 arcs @Thickness 1.50 mm	>= 120 arcs @Thickness 0.0591 in	UL Rating PLC 0 (>120 arcs)
High Voltage Arc-Tracking Rate, HVTR	10.0 - 25.4 mm/min @Thickness 3.00 mm	0.394 - 1.00 in/min @Thickness 0.118 in	UL Rating PLC 1 (10-25.4 mm/min.)

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