

Covestro Apec® DP9-9340R High-Heat Polycarbonate, Medical with Release

Polymer, Thermoplastic, Polycarbonate (PC), Polycarbonate, High Heat

Covestro

产品说明

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 determine its suitability for use. As of 1 September 2015, Bayer MaterialScience was separated from Bayer AG and has officially adopted its new name – Covestro. This product was discontinued prior to the separation.

物理性能	额定值 (公制)	额定值 (英制)	测试方法
密度	1.17 g/cc	0.0423 lb/in ³	ASTM D792
吸水率	0.20 %	0.20 %	24 hour immersion; ASTM D570
线性成型收缩率	0.0070 - 0.0080 cm/cm	0.0070 - 0.0080 in/in	ASTM D955
熔体流动速率	15 g/10 min @Load 2.16 kg, Temperature 330 °C	15 g/10 min @Load 4.76 lb, Temperature 626 °F	ASTM D1238
机械性能	额定值 (公制)	额定值 (英制)	测试方法
洛氏硬度(M 级)	83	83	ASTM D785
洛氏硬度(R 级)	127	127	ASTM D785
极限抗拉强度	64.0 MPa	9280 psi	ASTM D638
抗张强度(屈服)	66.0 MPa	9570 psi	ASTM D638
伸长率 (断裂)	80 %	80 %	ASTM D638
屈服伸长率	6.0 %	6.0 %	ASTM D638
拉伸模量	2.20 GPa	319 ksi	ASTM D638
弯曲强度	86.0 MPa	12500 psi	ASTM D790
弯曲模量	2.28 GPa	331 ksi	ASTM D790
悬臂梁缺口冲击强度	3.20 J/cm @Thickness 3.17 mm	5.99 ft-lb/in @Thickness 0.125 in	ASTM D256
悬臂梁无缺口冲击强度	NB	NB	ASTM D256
	NB @Temperature -40.0 °C	NB @Temperature -40.0 °F	ASTM D256
电气性能	额定值 (公制)	额定值 (英制)	测试方法
电阻率	>= 1.00e+16 ohm-cm	>= 1.00e+16 ohm-cm	ASTM D257
表面电阻	>= 1.00e+16 ohm	>= 1.00e+16 ohm	ASTM D257
介电常数	2.9 @Frequency 60 Hz	2.9 @Frequency 60 Hz	ASTM D150
	2.9 @Frequency 1e+6 Hz	2.9 @Frequency 1e+6 Hz	ASTM D150
介电强度	>= 16.0 kV/mm @Thickness 3.17 mm	>= 406 kV/in @Thickness 0.125 in	ASTM D149
耗散因数	0.0010 @Frequency 60 Hz	0.0010 @Frequency 60 Hz	ASTM D150
	0.010 @Frequency 1e+6 Hz	0.010 @Frequency 1e+6 Hz	ASTM D150
热性能	额定值 (公制)	额定值 (英制)	测试方法
线性热膨胀系数	70.0 µm/m-°C @Temperature 20.0 °C	38.9 µin/in-°F @Temperature 68.0 °F	ASTM D696
载荷下热变形温度(0.46 MPa)	162 °C @Thickness 3.20 mm	324 °F @Thickness 0.126 in	ASTM D648

载荷下热变形温度(1.8 MPa)	150 °C @ Thickness 3.17 mm	302 °F @ Thickness 0.125 in	ASTM D648
维卡软化温度	172 °C	342 °F	Rate B; ASTM D1525
极限氧指数	24 %	24 %	ASTM D2863
光学性能	额定值 (公制)	额定值 (英制)	测试方法
折射率	1.578	1.578	ASTM D542
雾度	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
加工性能	额定值 (公制)	额定值 (英制)	测试方法
加工(熔体)温度	310 - 330 °C	590 - 626 °F	