Makrolon Rx1805

Grades / Medical devices	Global grade; MVR (300 °C/1.2 kg) 6.0 cm³/10 min; medical devices; high lipid resistance; suitable for sterilization with high-energy radiation; biocompatible according to many ISO 10993-1 test requirements; high viscosity; injection molding - melt temperature 280 - 320 °C; available in color code 451118 only; transparent parts for medical devices
ISO Shortname	ISO 7391-PC,M,(,,)-09-9

Property	Test Condition	Unit	Standard	Value
Rheological properties				
Melt mass-flow rate	300 °C; 1.2 kg	g/10 min	ASTM D1238	6.5
Mold shrinkage, flow/cross to flow		in/in	ASTM D955	0.006-0.008
Mechanical properties (23 °C/50 % r. h.)				
Tensile modulus	1 mm/min	lb/in²	ASTM D638	350000
Tensile stress at yield	-	lb/in²	ASTM D638	9400
Tensile elongation at yield	-	%	ASTM D638	6.0
Tensile elongation at break	-	%	ASTM D638	120
Tensile stress at break	-	lb/in²	ASTM D638	10200
Izod notched impact strength	73 °F, 0.125 in	ft·lb/in	ASTM D256	18
Flexural modulus	-	lb/in²	ASTM D790	340000
Flexural stress at 5 % strain		lb/in²	ASTM D790	13000
Thermal properties				
Deflection temperature under load, Unannealed	264 psi; 0.250 in	°F	ASTM D648	259
Deflection temperature under load, Unannealed	66 psi; 0.250 in	°F	ASTM D648	273
Vicat softening temperature	50 N, 50 °C/h	°F	ASTM D1525	291
Coefficient of linear thermal expansion, flow/cross-flow		in/in/°F	ASTM D696	3.34E-05
Thermal conductivity		Btu·in/(h·ft²·°F)	ASTM C177	1.39
Specific heat		Btu/(lb·°F)	ASTM D2766	0.28
Other properties (23 °C)				
Water absorption	73 °F; immersion to saturation	%	ASTM D570	0.3
Water absorption	73 °F; immersion 24 h	%	ASTM D570	0.12
Density		lb/in³	ASTM D792	0.043
Specific volume		in³/lb	ASTM D792	23.1
Specific gravity		-	ASTM D792	1.2
Material specific properties				
Luminous transmittance (clear transparent materials)	0.125 in	%	ASTM D1003	76

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Disclaimer

General

The manner in which you use and the purpose to which you put and utilize our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance and information to determine to your own satisfaction whether they are suitable for your intended uses and applications. This application-specific analysis must at least include testing to determine suitability from a technical as well as health, safety and environmental standpoint. Such testing has not necessarily been done by us. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee, and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance and information. Any statement or recommendation not contained herein is unauthorized and shall not bind us. Nothing herein shall be construed as a recommendation to use any product in conflict with patents covering any material or its use. No license is implied or in fact granted under the claims of any patent. Unless specified to the contrary, the property values given have been established on standardized test specimens at room temperature. The figures should be regarded as typical values only and not as binding limiting values. Please note that the properties can be affected by the design of the mold/die, the processing conditions and coloring. With respect to health, safety and environment precautions, the relevant Material Safety Data Sheets (MSDS) and product labels must be observed prior to working with our products.

BMS Medical Grades

BMS Products that are designated as "Medical Grade", e.g., plastics, sheets, and films, meet certain biocompatibility test requirements of ISO Standard 10993-1: "Biological Evaluation of Medical Devices" for the categories including: (1) skin contact, (2) up to 24 hours contact with circulating blood, tissue, bone, and dentin, (3) up to 30 days contact with mucosal membranes, compromised surfaces, and blood path, indirect. BMS Products designated as "Medical Grade" shall not be considered candidates for the following types of Medical Applications unless BMS explicitly agrees, in writing, to sell such products for such applications: (a) cosmetic, reconstructive, or reproductive implant applications; (b) any other bodily implant applications; (c) applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days; or (d) applications having greater than 24 hours contact with circulating blood, tissue, bone and dentin. The biocompatibility testing referenced above cannot assure the biocompatibility of final or intermediate products made from BMS Products or the suitability of such products for their use in a Medical Application, i.e., the test data cannot be used to conclude that any medical devices manufactured from the BMS Products meet the necessary requirements of ISO Standard 10993-1. It is the sole responsibility of the manufacturer of final end-use product to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements. The designation as "Medical Grade" does not mean that BMS or anyone else has determined that the product is suitable for use in any particular Medical Application. BMS makes no representations regarding the suitability of a BMS Product for a particular Medical Application or final enduse product. A determination that the BMS Product is suitable for use in a particular Medical Application or final end-use product can only be made by the purchaser of the BMS product who utilizes it in a Medical Application and conducts all necessary testing and evaluation to support such a determination.

Appropriate Use of BMS Products in a Medical Application

BMS has not performed clinical medical studies concerning the use of BMS Products. Moreover, BMS has neither sought nor received approval from the United States Food and Drug Administration (FDA) or other competent authorities from other regions for the use of BMS Products in a Medical Application. BMS makes no representations or warranty regarding (and accepts no responsibility for determining) either: (a) the suitability of a BMS Product for a particular Medical Application or final end-use product or (b) the adequacy of any warning relating to a BMS Product or particular Medical Application or final end-use product. The suitability of BMS Products in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, method of manufacture, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final end-use product to determine the suitability (including biocompatibility) of all raw materials and components, including any BMS Products, in order to ensure that the final product: - meets relevant biocompatibility requirements and is otherwise safe for its end-use, - performs or functions as intended, - is suitable for its intended use, and - complies with all applicable FDA and other regulatory requirements. It also is the sole responsibility of the manufacturer of the final end-use product to conduct all necessary tests and inspections and to evaluate the final product under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular medical product in a particular clinical or Medical Application should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician. BMS cannot weigh the benefits against the risks of a medical device and cannot offer a medical or legal judgment on the safety or efficacy of the use of a BMS Product in a specific Medical Application. Terms in capital letters as used herein shall have the same meaning as defined in the "GUIDANCE ON USE OF BAYER MATERIALSCIENCE PRODUCTS IN A MEDICAL APPLICATION" which can be found under (http://www.bayermaterialscience.de/internet/global_portal_cms.nsf/id/Literature_en/$file/GUIDANCE.pdf). It is the customer's responsibility to thoroughly review the Guidance Document in detail and to diligently consider its content prior to any use of BMS Products in Medical Applications. For further information on our Medical Grades please see our brochure "Makrolon, Apec and Bayblend for medical devices" under (https://plastics.bayer.com/plastics/emea/en/library/brochures/docId-68388/MS00041261.pdf?docPart=0)."

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