Makrolon® 3158

Grades / Medical devices	MVR (300 °C/1.2 kg) 6.0 cm³/10 min; medical devices; suitable for ETO and steam sterilization at 121 °C; biocompatible according to many ISO 10993-1 test requirements; high viscosity; easy release; injection molding - melt temperature 280 - 320 °C; available in transparent and opaque colors
ISO Shortname	ISO 7391-PC,MR,(,,)-09-9

	Property	Test Condition	Unit	Standard	typical Value
Rheological properties					-
C	Melt volume-flow rate	300 °C; 1.2 kg	cm³/10 min	ISO 1133	6.0
C	Molding shrinkage, parallel	60x60x2 mm; 500 bar	%	ISO 294-4	0.7
C	Molding shrinkage, normal	60x60x2 mm; 500 bar	%	ISO 294-4	0.75
	Molding shrinkage, parallel/normal	Value range based on general practical experience	%	b.o. ISO 2577	0.6 - 0.8
	Melt mass-flow rate	300 °C; 1.2 kg	g/10 min	ISO 1133	6.5
Mechanical properties (23 °C/50 % r. h.)					
C	Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	2400
C	Yield stress	50 mm/min	MPa	ISO 527-1,-2	66
C	Yield strain	50 mm/min	%	ISO 527-1,-2	6.2
C	Nominal strain at break	50 mm/min	%	ISO 527-1,-2	> 50
	Stress at break	50 mm/min	MPa	ISO 527-1,-2	70
	Strain at break	50 mm/min	%	b.o. ISO 527-1,-2	120
C	Tensile creep modulus	1 h	MPa	ISO 899-1	2200
C	Tensile creep modulus	1000 h	MPa	ISO 899-1	1900
	Flexural modulus	2 mm/min	MPa	ISO 178	2400
	Flexural strength	2 mm/min	MPa	ISO 178	97
	Flexural strain at flexural strength	2 mm/min	%	ISO 178	7.1
	Flexural stress at 3.5 % strain	2 mm/min	MPa	ISO 178	73
C	Charpy impact strength	23 °C	kJ/m²	ISO 179-1eU	N
C	Charpy impact strength	-30 °C	kJ/m²	ISO 179-1eU	N
	Charpy impact strength	-60 °C	kJ/m²	ISO 179-1eU	N
	Charpy notched impact strength	23 °C; 3 mm	kJ/m²	ISO 7391/b.o. ISO 179-1eA	80P
	Charpy notched impact strength	-30 °C; 3 mm	kJ/m²	ISO 7391/b.o. ISO 179-1eA	16C
	Izod notched impact strength	23 °C; 3.2 mm	kJ/m²	b.o. ISO 180-A	90P
	Izod notched impact strength	-30 °C; 3.2 mm	kJ/m²	b.o. ISO 180-A	14C
C	Puncture maximum force	23 °C	N	ISO 6603-2	5600
C	Puncture maximum force	-30 °C	N	ISO 6603-2	6500
C	Puncture energy	23 °C	J	ISO 6603-2	60
C	Puncture energy	-30 °C	J	ISO 6603-2	70
	Ball indentation hardness		N/mm²	ISO 2039-1	113
Thermal properties					
C	Glass transition temperature	10 °C/min	°C	ISO 11357-1,-2	146
C	Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	126
C	Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	138
C	Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	147
	Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	148
C	Coefficient of linear thermal expansion, parallel	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.65
C	Coefficient of linear thermal expansion, transverse	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.65
	Thermal conductivity, cross-flow	23 °C; 50 % r. h.	W/(m·K)	ISO 8302	0.20
	Resistance to heat (ball pressure test)		°C	IEC 60695-10-2	138
	Flash ignition temperature		°C	ASTM D1929	480
	Self ignition temperature		°C	ASTM D1929	550

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	Property	Test Condition	Unit	Standard	typical Value
Other properties (23 °C)					
C	Water absorption (saturation value)	Water at 23 °C	%	ISO 62	0.30
C	Water absorption (equilibrium value)	23 °C; 50 % r. h.	%	ISO 62	0.12
C	Density		kg/m³	ISO 1183-1	1200
	Bulk density	Pellets	kg/m³	ISO 60	660
Material specific properties					
	Refractive index	Procedure A	-	ISO 489	1.587
	Haze for transparent materials	3 mm	%	ISO 14782	< 0.8
	Luminous transmittance (clear transparent materials)	1 mm	%	ISO 13468-2	89
C	Luminous transmittance (clear transparent materials)	2 mm	%	ISO 13468-2	89
	Luminous transmittance (clear transparent materials)	3 mm	%	ISO 13468-2	88
	Luminous transmittance (clear transparent materials)	4 mm	%	ISO 13468-2	87
Processing conditions for test specimens					
C	Injection molding-Melt temperature		°C	ISO 294	300
C	Injection molding-Mold temperature		°C	ISO 294	80
C	Injection molding-Injection velocity		mm/s	ISO 294	200

C These property characteristics are taken from the CAMPUS plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

Impact properties: N = non-break, P = partial break, C = complete break

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Disclaimer

Information Impact properties

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Typical value

These values are typical values only. Unless explicitly agreed in written form, the do not constitute a binding material specification or warranted values. Values may be affected by the design of the mold/die, the processing conditions and coloring/pigmentation of the product. Unless specified to the contrary, the property values given have been established on standardized test specimens at room temperature.

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 our products, technical assistance and information 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 any claim of any patent relative to any material or its use. No license is implied or in fact granted under the claims of any patent.

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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.

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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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