

# Makrolon 2558

**Grades / Medical devices** 

Global grade; MVR (300 °C/1.2 kg) 14.5 cm³/10 min; medical devices; suitable for ETO and steam sterilization at 121 °C; biocompatible according to many ISO 10993-1 test requirements; medium viscosity; easy release; injection molding - melt temperature 280 - 320 °C; available in transparent and opaque colors

ISO Shortname

ISO 7391-PC,MR,(,,)-18-9

Property	Test Condition	Unit	Standard	Value -
neological properties				
Melt mass-flow rate	300 °C; 1.2 kg	g/10 min	ASTM D1238	15
Mold shrinkage, flow/cross to flow		in/in	ASTM D955	0.006-0.008
echanical 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 break	-	%	ASTM D638	115
Tensile stress at break	-	lb/in²	ASTM D638	8700
Izod notched impact strength	73 °F, 0.125 in	ft-lb/in	ASTM D256	16
Flexural modulus	-	lb/in²	ASTM D790	340000
Flexural stress at 5 % strain		lb/in²	ASTM D790	12500
Rockwell hardness		M Scale	ASTM D785	75
Rockwell hardness		R Scale	ASTM D785	120
nermal properties	•	•	1	'
Deflection temperature under load, Unannealed	264 psi; 0.250 in	°F	ASTM D648	266
Deflection temperature under load, Unannealed	66 psi; 0.250 in	°F	ASTM D648	275
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
UL94 Flame Class	Thickness tested: 1.5 mm	Class	UL 94	V-2
UL94 Flame Class	Thickness tested: 3.0 mm	Class	UL 94	НВ
UL94 Flame Class	Thickness tested: 6.0 mm	Class	UL 94	НВ
Oxygen index	İ	%	ASTM D2863	28
Thermal conductivity	İ	Btu-in/(h-ft²-°F)	ASTM C177	1.39
Specific heat		Btu/(lb·°F)	ASTM D2766	0.28
Relative temperature index (Tensile impact strength)	Thickness tested: 1.5 mm	°C ,	UL 746B	115
Relative temperature index (Tensile strength)	Thickness tested: 1.5 mm	°C	UL 746B	125
Relative temperature index (Electric strength)	Thickness tested: 1.5 mm	°C	UL 746B	125
ectrical properties (23 °C/50 % r. h.)	'-	L		
Dissipation factor, Tinfoil electrodes	60 Hz	1_	ASTM D150	0.0009
Dissipation factor, Tinfoil electrodes	1 MHz	-	ASTM D150	0.01
Dielectric constant, Tinfoil electrodes	60 Hz	-	ASTM D150	3.0
Dielectric constant, Tinfoil electrodes	1 MHz	-	ASTM D150	2.9
Volume resistivity, Tinfoil electrodes	. 1911 12	Ohm-m	ASTM D257	1.0E+14
Surface resistivity		Ohm	ASTM D257	1.0 E+16
Electrical strength	Short time under oil at 73 °F	V/mil	ASTM D149	810
<u>.                                    </u>	onor and and on acro 1	1	,	
ther properties (23 °C)	70.05.1	T <sub>o/</sub>	AOTAL DETC	1
Water absorption	73 °F; immersion to saturation	%	ASTM D570	0.3
Water absorption	73 °F; immersion 24 h	% Ib /i n 3	ASTM D700	0.12
Density  Specific volume		lb/in³	ASTM D792	0.043
Specific volume		in <sup>3</sup> /lb	ASTM D792	23.1
Specific gravity		-	ASTM D792	1.2
aterial specific properties				
Refractive index		-	ASTM D542	1.586
Luminous transmittance (clear transparent materials)	0.125 in	%	ASTM D1003	88
Haze for transparent materials	0.125 in	%	ASTM D1003	< 0.8

Page 1 of 2 pages



Edition 21.10.2010 ASTM Datasheet



# Makrolon 2558

#### 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 end-use 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 BM

## 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. 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 Med

Publisher: Global Innovations - Polycarbonates Bayer MaterialScience AG, D-51368 Leverkusen,

www.bayermaterialscience.com pcs-info@bayermaterialscience.com

Page 2 of 2 pages

**Makrolon**<sup>®</sup>

Edition 21.10.2010 ASTM Datasheet