

# Makrolon Rx1805

## Speciality grades / Medical devices

Global grade; MVR 6.0 cm<sup>3</sup>/10 min; Medical devices; Lipid resistant; Suitable for radiation sterilization; Complies with the requirements of FDA-modified ISO 10993-1 and USP Class VI; High viscosity; Injection molding; Transparent parts for medical devices

## ISO Shortname

ISO 7391-PC,M,(,,-)09-9

Property	Test Condition	Unit	Standard	Value
<b>Rheological properties</b>				
C Melt volume-flow rate	300 °C; 1.2 kg	cm <sup>3</sup> /(10 min)	ISO 1133	6.0
Molding shrinkage, parallel/normal	Value range based on general practical experience	%	acc. ISO 2577	0.6 - 0.8
Melt mass-flow rate	300 °C; 1.2 kg	g/(10 min)	ISO 1133	6.5
<b>Mechanical properties (23 °C/50 % r. h.)</b>				
C Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	2350
C Yield stress	50 mm/min	MPa	ISO 527-1,-2	66
C Yield strain	50 mm/min	%	ISO 527-1,-2	6.3
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	%	acc. ISO 527-1,-2	115
Flexural modulus	2 mm/min	MPa	ISO 178	2300
Flexural strength	2 mm/min	MPa	ISO 178	98
Flexural strain at flexural strength	2 mm/min	%	ISO 178	7.0
Flexural stress at 3.5 % strain	2 mm/min	MPa	ISO 178	74
C Charpy impact strength	23 °C	kJ/m <sup>2</sup>	ISO 179-1eU	N
C Charpy impact strength	-30 °C	kJ/m <sup>2</sup>	ISO 179-1eU	N
Charpy notched impact strength	23 °C; 3 mm	kJ/m <sup>2</sup>	acc. ISO 179-1eA	75P
Charpy notched impact strength	-30 °C; 3 mm	kJ/m <sup>2</sup>	acc. ISO 179-1eA	14C
Izod notched impact strength	23 °C; 3.2 mm	kJ/m <sup>2</sup>	acc. ISO 180-A	85P
Izod notched impact strength	-30 °C; 3.2 mm	kJ/m <sup>2</sup>	acc. 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	6600
C Puncture energy	23 °C	J	ISO 6603-2	60
C Puncture energy	-30 °C	J	ISO 6603-2	70
Ball indentation hardness		N/mm <sup>2</sup>	ISO 2039-1	115
<b>Thermal properties</b>				
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	137
C Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	145
Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	146
C Coefficient of linear thermal expansion, parallel	23 to 55 °C	10 <sup>-4</sup> /K	ISO 11359-1,-2	0.65
C Coefficient of linear thermal expansion, transverse	23 to 55 °C	10 <sup>-4</sup> /K	ISO 11359-1,-2	0.65
C Oxygen index	Method A	%	ISO 4589-2	27
Thermal conductivity	23 °C	W/(m·K)	ISO 8302	0.20
Resistance to heat (ball pressure test)		°C	IEC 60695-10-2	135
Flash ignition temperature	Procedure B	°C	ASTM D1929	470
Self ignition temperature	Procedure B	°C	ASTM D1929	520
<b>Other properties (23 °C)</b>				
C Water absorption (Saturation value)	Water at 23 °C	%	ISO 62	0.30
C Water absorption (Equilibrium value)	23 °C; 50 % RH	%	ISO 62	0.12
C Density		kg/m <sup>3</sup>	ISO 1183	1200
Bulk density	Pellets	kg/m <sup>3</sup>	ISO 60	640
<b>Processing conditions for test specimens</b>				
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



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plastics according to ISO 10350.



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## Disclaimer

Disclaimer for Sales products

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Test values

Unless specified to the contrary, the values given have been established on standardised test specimens at room temperature. The figures should be regarded as guide values only and not as binding minimum values. Kindly note that, under certain conditions, the properties can be affected to a considerable extent by the design of the mould/die, the processing conditions and the colouring.

Medical products

\*\*Only Bayer plastics which fulfil the test requirements of ISO 10 993-1 may be used for medical articles which come within the scope of this standard. Applications involving long-term contact for which Bayer plastics are not intended are exceptions. However, the biocompatibility tests which we perform according to this standard do not cover the following ranges of application for medical articles manufactured from our material: Long-term use over 30 days, particularly use as (cosmetic or reconstructive) implant Long-term contact over 30 days with endogenous substances (blood, tissue, dentin, other body fluids) Multiple use for medical applications Therefore Bayer plastics should not be used for long-term applications or with long-term contact. Use of recycled material and incompatible additives Our test results for biocompatibility do not apply to the use of recycled materials or the use of other additional material components in the finished product. Responsibility of the manufacturer of the medical article The use of our material outside the above-mentioned test scope of ISO 10 993-1 occurs exclusively on the responsibility of the processor of our material and the manufacturer of the finished product. As regards the production conditions of the processor of our material which are not known to us, it is the responsibility of the processor to ascertain the suitability of our materials in the finished product in terms of directives and statutes to be observed. The suitability of our materials also depends on the ambient conditions (see below) for the finished product. Chemical compatibility, temperature, design of the medical article, method of sterilization, internal stress within the finished article, and external stress all influence suitability, and are therefore the responsibility of the processor and the manufacturer of the finished product. Multiple-use of medical articles Medical articles which are intended for single use and which were manufactured from Bayer plastic are not suitable for multiple use. If the medical article was manufactured for multiple use, it is the responsibility of the manufacturer of the finished product to determine an appropriate number of times it may be used, by determining and evaluating the conditions of sterilization and final use. Appropriate warnings and instructions must be given to the final user. Sterilization The use of various methods of sterilization and the permitted number of sterilization cycles for a medical article which is made from our materials depend on the design of the parts, the processing parameters, the sterilization temperature and the chemical environment. Therefore the manufacturer must determine and evaluate the most suitable method of sterilization (and if applicable the permitted number of sterilization cycles) for each medical article. Appropriate instructions and warnings must be given to the final user.

Processing note

Under the recommended processing conditions small quantities of decomposition product may be given off during processing. To preclude any risk to the health and well-being of the machine operatives, tolerance limits for the work environment must be ensured by the provision of efficient exhaust ventilation and fresh air at the workplace in accordance with the Safety Data Sheet. In order to prevent the partial decomposition of the polymer and the generation of volatile decomposition products, the prescribed processing temperatures should not be substantially exceeded. Since excessively high temperatures are generally the result of operator error or defects in the heating system, special care and controls are essential in these areas.

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