Makrolon® Rx2530

- **Polycarbonate (PC)**
- **Medium viscosity**
- **Injection molding**
- **Medical devices****

Short description

Makrolon® Rx2530:

Global grade; MVR 14.5 cm³/10 min; Medical devices; suitable for sterilization with high-energy radiation; Complies with the requirements of FDA-modified ISO 10993-1 and USP Class VI; Medium viscosity; Injection molding - Melt temperature 280 - 320 °C; Available in color code 451118 only; Transparent parts for medical devices

Characterization

Makrolon® Rx2530 is a transparent, medium viscosity polycarbonate on the basis of bisphenol A with a special additive system.

It has been developed for applications in medical technology, and particularly for medical engineering articles capable of γ radiation sterilization.

Makrolon® Rx2530 can be sterilized by the usual methods, for example with steam (121 °C) or ethylene oxide gas. It is also suitable for sterilization using high energy radiation, such as γ radiation. In addition, it has higher color stability after radiation than standard polycarbonates.

The adhesives and solvents normally used for medical applications of polycarbonate can also be employed to produce a reliable bond between components made of Makrolon® Rx2530 and e.g. plasticized PVC tubing.

Makrolon® Rx2530 was tested according to the FDA-Modified ISO 10993-1 and USP Class VI tests, and meets the requirements specified for up to 30 days contact with human tissue.

Abbreviation to DIN EN ISO 1043-1: PC

Designation to DIN EN ISO 7391-1:
Thermoplastics ISO 7391-PC,M,(,,)-18-9

Delivery form

Granules, packed in 25-kg polyethylene sacks, FIBC (flexible intermediate bulk containers – big bags), large cartons with a polyethylene inliner or in bulk.

All Makrolon® batches are homogenized after production.

Makrolon® Rx2530 is supplied in the color code 451118.

The production plants for Makrolon® have been certificated to DIN ISO by the appropriate quality organizations. The certificates can be found in the INTERNET at http://www.bayermaterialscience.com
(Customer Services / Certificates).

Registered customers can access Safety Data Sheet on the Internet (bayerone.bayer.com). It can also be sent on request.
The Safety Data Sheet includes data on labeling, transport and storage, as well as information on handling, product safety and toxicological and ecological profiles.

Applications

Makrolon® Rx2530 is a special product for medical devices**. It can be used for the production of, for example, centrifugation systems and ampoules for a needle-free injection system.

** See Disclamer

File No. PCS-8054 en (replaces TI KU28054 dated 2004-09-21)

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Biocompatibility

All Bayer resins, films, etc. (hereinafter "Products") designated as "medical-grade" have met the requirements of the FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. These tests are conducted under Good Laboratory Practices as defined by the FDA in 21 CFR Part 58. The products were sterilized by ethylene oxide and gamma radiation prior to testing. Only these Products may be considered candidates for applications requiring biocompatibility. No "medical-grade" Product will be available for sale until successful completion of testing.
Regrind resins must not be used in medical applications requiring biocompatibility.
FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less have largely supplanted older USP Plastics Class VI and other standards for biocompatibility.

These tests include:

- Acute system toxicity
- Intracutaneous toxicity
- Muscle implantation
- Cytotoxicity - (MEM Elution)
- Hemolysis - direct and extraction
- Physicochemical tests
- Heavy metal analysis
- Pyrogen study
- Sensitization (maximization method)
  - saline extract, oil extract
- Mutagenicity, Ames test
  - saline extract, and 95 % ethanol extract

Test data will be mailed on request.

Disinfection and Sterilization

Moldings made of Makrolon® Rx2530 can be disinfected and sterilized by most of the familiar methods used in practice. Under certain conditions, damage to the molding can occur in contact with disinfectants and through sterilization. The major factors here are the chemical constituents and their concentration in the disinfectant, as well as the internal stress state of the moldings, the mechanical load and the temperature during the contact.

Disinfection[1)]

Depending on their composition, certain disinfectants may damage Makrolon® Rx2530 moldings. A certain amount of caution is needed with some products containing aldehydes, phenols or amines as the active ingredient. Otherwise, tests show that Makrolon® is compatible with the large majority of conventional disinfectants.

Sterilisation[1)]

Makrolon® Rx2530 can be sterilized by the normal processes with steam (121 °C), ethylene oxide gas or high energy radiation, e.g. γ radiation.

The applicability of various sterilization methods and the number of permitted sterilization cycles in the case of multiple use of the product made from our materials will depend on the design of the component, the processing parameters, sterilization temperature and chemical environment. This means that the manufacturer must establish and evaluate the most suitable sterilization method for each medical product (and possibly the number of permitted sterilization cycles).

Appropriate instructions for use and warnings must be passed on to the end-user.

Medical articles which are intended for single use and which were manufactured from Bayer plastic are not suitable for multiple uses.

1) Details on this can be found in our Technical Information Sheet.

"Plastics for medical devices"
"Cleaning, Disinfection and Sterilization of Parts in Makrolon®"
"The chemical resistance of Makrolon®"

Processing

Pre-treatment / drying[2)]

Makrolon® must be dried prior to processing. For injection molding no more than 0.02 % residual moisture may be present in the granules and, for extrusion, no more than 0.01 %. Moisture in the melt leads to surface defects as well as to a greater reduction in molecular weight.

Makrolon® should be dried in suitable dryers at 120 °C.

The drying time for moist granules is largely a function of the nature and type of the drying unit and can total 2 to 12 hours depending on the drying capacity. Drying times of 2 to 4 hours are sufficient in modern high-speed dryers. One means of dispensing with pre-drying is for the moisture to be removed during melting with the aid of a degassing unit, as has been standard practice in extrusion for a long time.

Injection molding[2)]

Makrolon® can be processed on all modern injection molding machines. Shut-off nozzles are suitable given sufficient, uniform heating. At high melt temperatures, melt can flow out of open nozzles. Molding shrinkage is more or less identical in all directions and amounts to between 0.6 and 0.8 %.

The melt temperatures generally employed during processing are between 280 and 320 °C.

Material damage has to be expected with excessively high processing temperatures or excessively long residence times in the cylinder and hot runner. This can lead to a reduction in toughness and/or to surface defects in the form of streaks.

It should be possible for the molds to be heated intensively and uniformly, and the mold temperature should be at least 80 °C to ensure parts with a low inherent stress and a good surface. No demolding difficulties are encountered at up to 120 °C.

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.

2) Details on this can be found in our Technical Information Sheet.

"Determining the dryness of Makrolon® by the TVI test"
"Processing data for the injection molder"
"The Injection Molding of High-Quality Molded Parts"

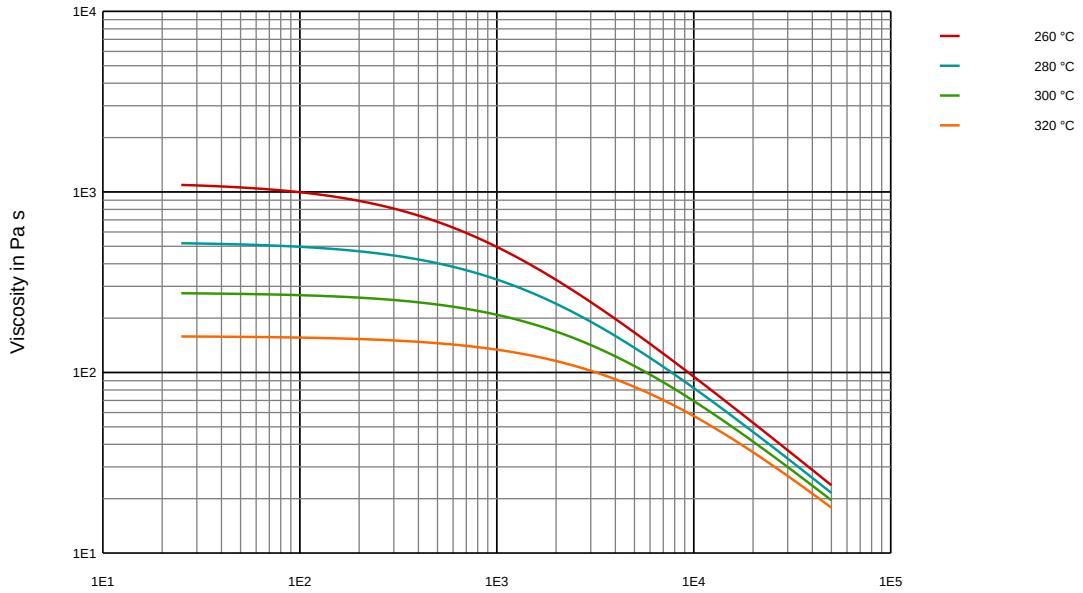

Fig. 1: Melt viscosity as a function of shear rate (Makrolon® Rx2530)

Typical Values

	Property	Test Condition	Unit	Standard	Makrolon® Rx2530
Rheological properties					
C	Melt volume-flow rate	300 °C; 1.2 kg	cm³/10 min	ISO 1133	14.5
C	Molding shrinkage, parallel	60x60x2; 500 bar	%	ISO 294-4	0.6
C	Molding shrinkage, normal	60x60x2; 500 bar	%	ISO 294-4	0.65
	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	15.5
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	67
C	Yield strain	50 mm/min	%	ISO 527-1,-2	6.1
C	Nominal strain at break	50 mm/min	%	ISO 527-1,-2	> 50
	Stress at break	50 mm/min	MPa	ISO 527-1,-2	75
	Strain at break	50 mm/min	%	b.o. ISO 527-1,-2	130
	Flexural modulus	2 mm/min	MPa	ISO 178	2400
	Flexural strength	2 mm/min	MPa	ISO 178	100
	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/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	b.o. ISO 179/1eA	70P
	Charpy notched impact strength	-30 °C; 3 mm	kJ/m²	b.o. ISO 179/1eA	14C
	Izod notched impact strength	23 °C; 3.2 mm	kJ/m²	b.o. ISO 180/A	80P(C)
	Izod notched impact strength	-30 °C; 3.2 mm	kJ/m²	b.o. ISO 180/A	12C
C	Puncture maximum force	23 °C	N	ISO 6603-2	5300
C	Puncture maximum force	-30 °C	N	ISO 6603-2	6200
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	118
Thermal properties					
C	Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	122
C	Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	134
C	Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	141
	Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	142
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	23 °C	W/(m·K)	ISO 8302	0.20
	Resistance to heat (ball pressure test)		°C	IEC 60695-10-2	132
	Flash ignition temperature		°C	ASTM D1929	480
	Self ignition temperature		°C	ASTM D1929	550
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	1200
	Bulk density	Pellets	kg/m³	ISO 60	660

Typical Values

	Property	Test Condition	Unit	Standard	Makrolon® Rx2530
Processing conditions for test specimens					
C	Injection molding-Melt temperature		°C	ISO 294	280
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

This information and our technical advice - whether verbal, in writing or by way of trials - are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. Our advice does not release you from the obligation to check its validity and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice are beyond our control and, therefore, entirely your own responsibility. Our products are sold in accordance with the current version of our General Conditions of Sale and Delivery.

**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. 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 materials or the use of other additional material components in the finished product: 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 end 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 end user.

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

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.

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