Makrolon® 3208

- **Polycarbonate (PC)**
- **General purpose grades**
- **High viscosity**
- **Extrusion**
- **Injection molding**

Characterization

Makrolon® 3208 is a high viscosity, linear polycarbonate on the basis of bisphenol A with good hydrolysis resistance.

Makrolon® 3208 possesses the highest melt viscosity of any of the linear polycarbonates and has a higher level of mechanical properties than the other Makrolon® grades.

Makrolon® 3208 is an "FDA grade" which fulfills the requirements of the EU countries (including the BfR recommendations) and the FDA regulations for materials in contact with foodstuffs.

Abbreviation to DIN EN ISO 1043-1: PC

Designation to DIN EN ISO 7391-1:
Thermoplastics ISO 7391-PC,G,67-05-9

Additional information

The Makrolon® range includes not only the high viscosity Makrolon® 3208 but also the high viscosity 31.. series of grades. Special Makrolon® grades are available for extrusion and coextrusion

Details on this can be found in our Technical Information Sheets
"Makrolon® 3103, 3105, 3107, 3108 and 3158"
"Makrolon® 3103 MAS157, 1243, DP1-1816* and DP1-1852*".

Delivery form

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

All batches of Makrolon® are homogenized after production.

Makrolon® 3208 is only available in colors which, in terms of the coloring agents used, fulfill the FDA regulations for food contact at service temperatures of up to 100 °C.

The production plants for Makrolon® have been certificated to DIN ISO by the appropriate quality organizations.

Applications

The high melt viscosity of Makrolon® 3208 means that this grade is particularly suited to processing by extrusion and can be used to manufacture sheet and profiles.

The flow behavior of Makrolon® 3208, however, will also permit it to be processed on injection molding machines. If attaining the highest possible toughness represents the chief requirement on a PC molded part, then it is recommended that use be made of Makrolon® 3208 and that the design and mold be adapted to the short flow paths at the same time.

Makrolon® 3208 is suitable for food contact and medical devices**.

The Safety Data Sheet can be supplied on request.

** See Disclaimer for medical application

Properties (see Table)

Food legislation provisions

Parts in Makrolon® 3208 are odorless and tasteless and do not become discolored through normal contact with natural and synthetic coloring agents. While they do not display any defensive action vis-à-vis micro-organisms, they do not promote growth on their surface. Makrolon® 3208 can be used for the production of consumer goods for food contact.

1. For EU countries

Monomers used for the manufacture of plastics as well as a growing number of additives are regulated by EC Directives and their transformations into national ordinances, e.g. in Germany the "Ordinance on Consumer Goods" (Bedarfsgegenständeverordnung).

Since there are no finalized EC Directives covering all further plastics constituents (further additives, polymerization aids, colorants, etc.), these components have to comply with existing national rules/positive lists, which differ from one another in certain respects. In Germany for instance, the "BfR" (Bundesinstitut für Risikobewertung, formerly BgVV / BGA) recommendations are still to be observed for additives, etc.

With respect to its monomer and/or additive constituents Makrolon® 3208 complies with:

- Commission Directives 2002/72/EC*) of 06.08.2002 relating to plastics materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities, no. L 220/18, dated 2002)
  *) Directive 2002/72/EC consolidates and summarizes all earlier amendments to Directive 90/128/EEC
- (92/39/EEC, 93/9/EEC, 95/3/EC, 96/11/EC, 2001/62/EC and 2002/17/EC)
- the amended German "Ordinance on Consumer Goods" of 04.07.2003 (Federal Law Gazette, Part I, No. 14, 2003, pp. 486ff.).

The main sections of the above EC Directive and German Ordinance contain:

- the limit on "global migration": < 10 mg/dm² in relation to the surface of the article, and < 60 mg/kg in relation to the foodstuff
- the list of authorized monomers
- the incomplete list of authorized additives
- specific restrictions on individual monomers and additives (specific migration limits, SML, or, maximum residual content in finished plastic articles).

Regarding the monomers and/or the additives used in Makrolon® 3208, the following limits must be observed according to the Directive 2002/72/EC and the German Ordinance:

Carbonic acid dichloride -> max. residual content in the article:
< 1 mg/kg of plastic

Bisphenol A -> specific migration limit:
< 3 mg/kg of foodstuff

With respect to its further additives and/or further constituents, Makrolon® 3208 also complies with

- Recommendation XI, "Polycarbonate and mixtures of polycarbonates with polymers and copolymers", of the former German Federal Health Office (BgVV / BGA), now renamed the "Bundesinstitut für Risikobewertung" (BfR), status: 01.03.01 (202nd Communication: Bundesgesundh. Bl. 44, 546 (2001))

- Decreto Ministeriale dated 21.3.73 and its current supplements (Italy)
- Arrêté Royal of 25.08.1976 and its current supplements (Belgium)
- Verpakkingen- en Gebruiksartikelen-Besluit (Warenwet) dated 1.10.79 and its current supplements (Netherlands)
- Répression des Fraudes and its current supplements (France)
- Resolución de 04.11.1982 de la Subsecretaria para la Sanidad (Anexo) and its current supplements (Spain)

Evaluation:

At the moment, there are no recognized methods of analysis with sufficient precision for verifying these threshold values. This position seems unlikely to change in the near future. Methods of analysis are only

adopted as European standards at CEN once lengthy standardization procedures have been carried out following completion of the necessary round-robin trials.

For this reason, we are only able to make provisional and non-binding statements about our products based on our own investigations and product knowledge.

We are working on the assumption that the global migration and monomer-specific limit can be met when Makrolon® 3208 is used for food contact applications at room temperature or for short periods at temperatures of up to 100 °C.

2. For the USA

Makrolon® 3208 complies with FDA Regulation 21 CFR §177.1580 "Polycarbonate resins" for food contact applications up to 100 °C.

Not all color shades comply with the provisions of the FDA, the BfR (formerly BgVV / BGA) or the French positive list.

Processing

Pre-treatment / drying [1)]

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 an increased reduction in molecular weight. Makrolon® should be dried in suitable driers 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 driers. 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 [1)]

Makrolon® can be processed on all modern injection molding machines. 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.

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. It will not generally be necessary to employ mold release agents when Makrolon® grades with easy mold release are used.

When Makrolon® is processed under the recommended processing conditions it is possible for small quantities of breakdown products to be emitted. In accordance with the Safety Data Sheet, compliance with the specified exposure limits at the workplace must be guaranteed through adequate extraction and ventilation at the workplace, so as not to impair the health and well-being of the machine operators.

The specified processing temperatures must not be exceeded by any significant extent in order to pre-

vent greater partial decomposition of the polymer and the splitting off of volatile breakdown products. Since excessive temperatures are generally attributable to operating errors or to malfunctions in the heating system, particular care and monitoring is called for here.

[1] Details on this can be found in our Technical Information Sheets

"Determining the dryness of Makrolon® by the TVI test"
"The Injection Molding of High-Quality Molded Parts"

Extrusion[2]

The high viscosity Makrolon® grades are particularly suitable for processing by extrusion. Use is made solely of single-screw extruders. When it comes to temperature control, a barrel temperature profile which decreases from 280 °C at the hopper to 250 °C at the die, for instance, has proved successful. The downstream equipment, right through to the die, is best aligned to the temperature of the final barrel section. The melt temperature upon output from the die should be 240 °C to 300 °C as a function of the processing method. The extruder should be run until it is empty in the event of interruptions to production. It is recommended that all components in contact with the molten polycarbonate (extruder barrel, screen changer, melt pump, adapter, die) be kept at a temperature of 160 °C to 170 °C. Depending on the semi-finished product being manufactured, use can be made of different downstream units, such as smoothing calenders, sizing units and chill-roll systems. Annealing may be necessary in order to achieve warp-free semi-finished products, such as profiles. Film and sheet can generally be further processed by thermoforming.

[2] Details on this can be found in our Technical Information Sheet "The Extrusion of Bayer Thermoplastics".

Recycling/material disposal

Rejects and production waste can be reground, observing the drying and processing advice for virgin material, and made into new moldings. It is essential to check the property level and the color of molding compounds that contain regrind in respect of the envisaged application. The permissible regrind content must be established on a case-by-case basis.

When using regrind, it should be borne in mind that the grain geometry, which differs from that of extrusion granules, will influence the feed and plastification behavior. For this same reason, physical mixtures of regrind and granules tend to segregate on account of the movement they experience during transport, conveying and metering operations.

When Makrolon® is reprocessed, care should be taken to ensure that no foreign materials and no dirt is incorporated. Waste that contains pollutants and mixed waste can be chemically recycled or incinerated with energy recovery.

Non-recyclable Makrolon® waste can be disposed of in an environmentally compatible manner through the correct form of incineration and subsequent dumping of the slag.

Parts should be identified in accordance with DIN EN ISO 11469; the marking to be applied to parts in Makrolon® 3208 is as follows:

>PC<

Details on this can be found in our Technical Information Sheet "Part Identification of Thermoplastics for Recycling".

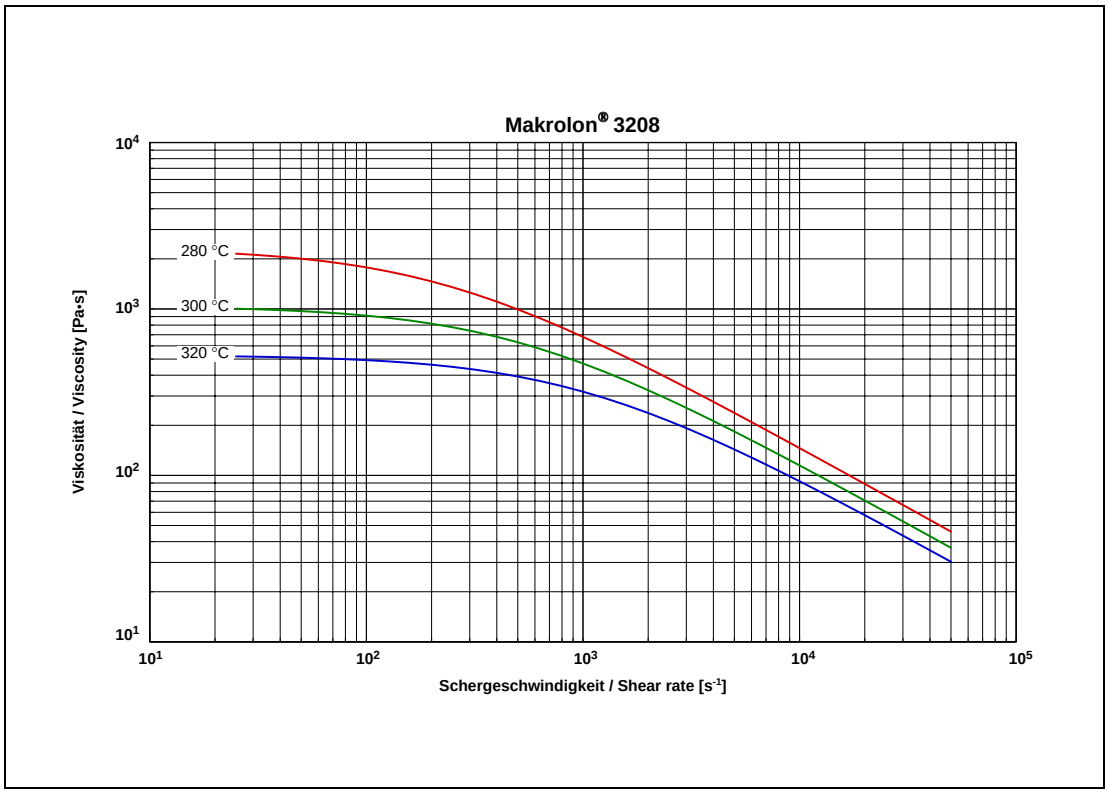

Fig. 1: Melt viscosity as a function of shear rate (Makrolon® 3208)

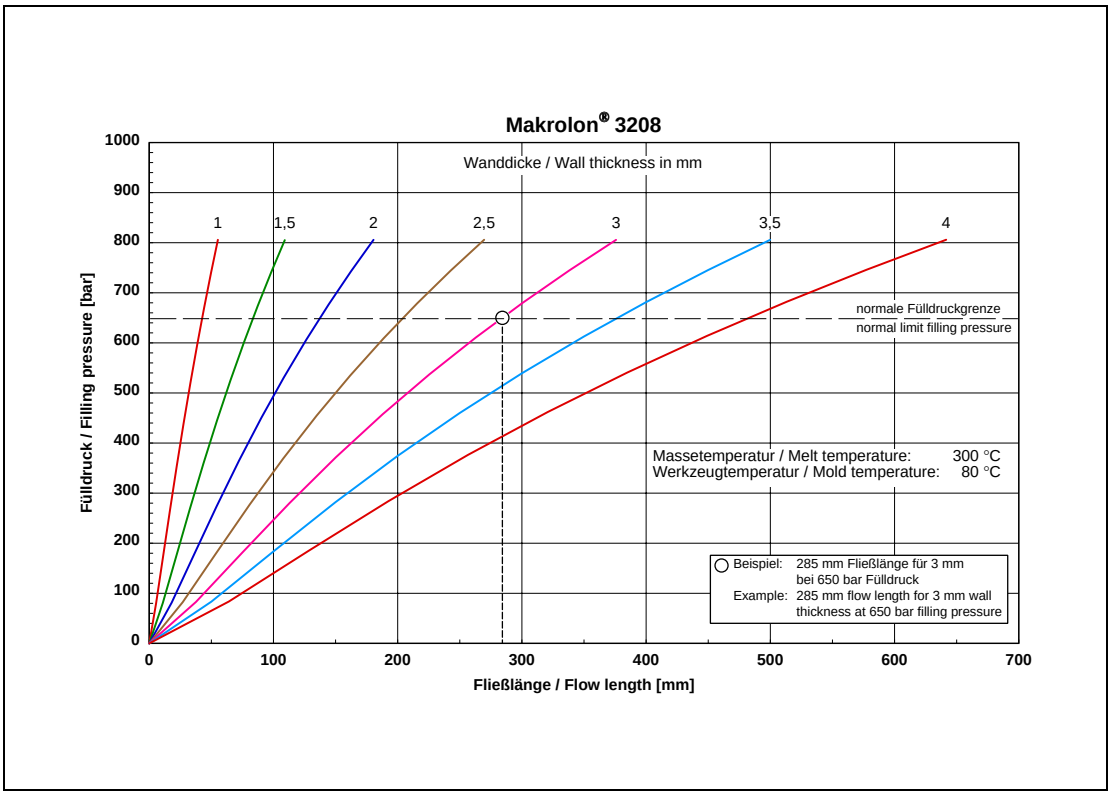

Fig. 2: Flow behavior - calculated values (Makrolon® 3208)

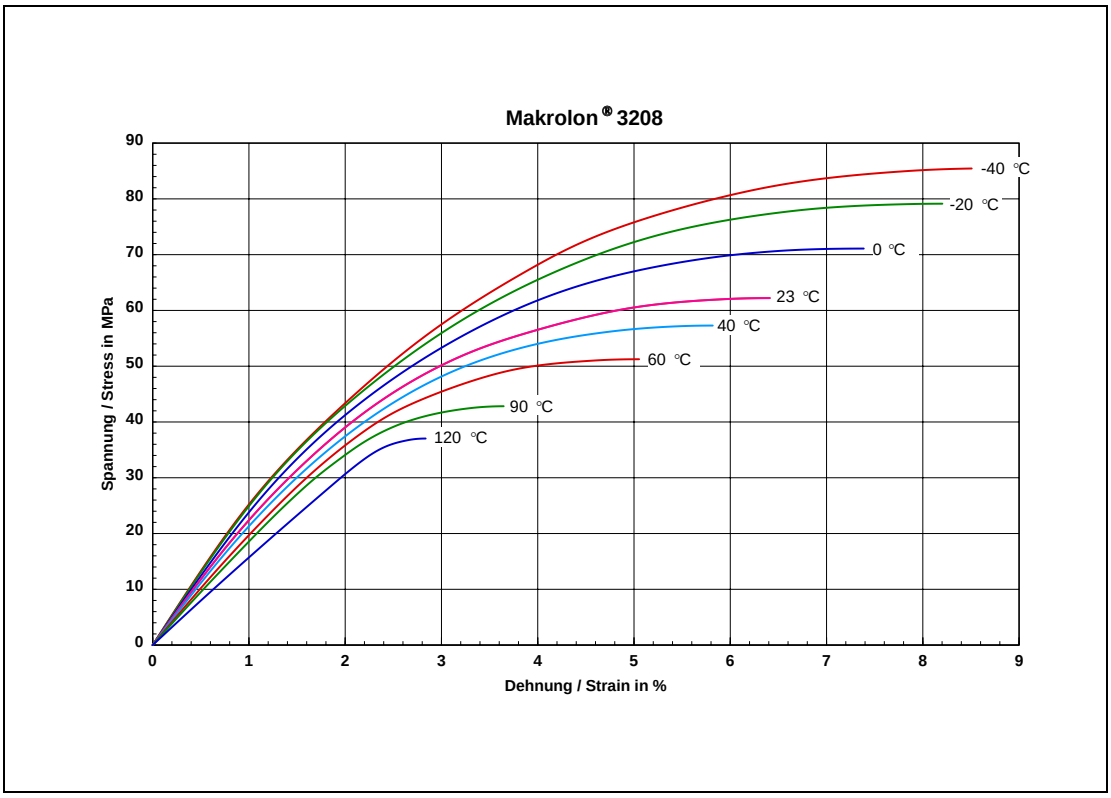

Fig. 3: Isothermal stress-strain curves from the short-time tensile test to ISO 527-1, -2 (Makrolon® 3208)

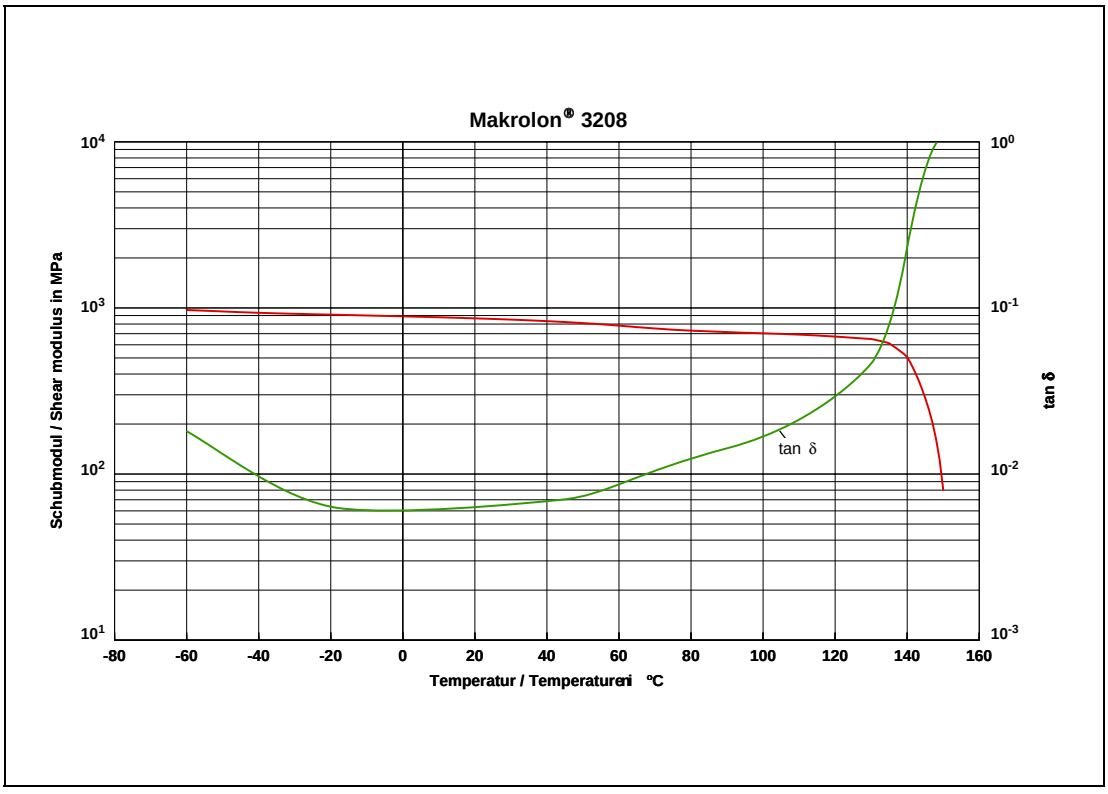

Fig. 4: Shear modulus as a function of temperature to ISO 6721-1, -2 (Makrolon® 3208)

Typical Values

	Properties	Test Conditions	Units	Standards	Makrolon® 3208
	Rheological properties				
C	Melt volume-flow rate	300 °C; 1.2 kg	cm³/(10 min)	ISO 1133	**4.0**
	Molding shrinkage, parallel/normal	Value range based on general practical experience	%	based ISO 2577	**0.6 - 0.8**
	Melt mass-flow rate	300 °C; 1.2 kg	g/(10 min)	ISO 1133	**4.5**
	Mechanical properties (23 °C/50 % r.h.)				
C	Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	**2350**
C	Yield stress	50 mm/min	MPa	ISO 527-1,-2	**65**
C	Yield strain	50 mm/min	%	ISO 527-1,-2	**6.4**
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	%	based ISO 527-1,-2	**115**
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	**2300**
	Flexural strength	2 mm/min	MPa	ISO 178	**98**
	Flexural strain at flexural strength	2 mm/min	%	ISO 178	**7.2**
	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 notched impact strength	23 °C; 3 mm	kJ/m²	based ISO 179-1eA	**75P**
	Charpy notched impact strength	-30 °C; 3 mm	kJ/m²	based ISO 179-1eA	**16C**
	Izod notched impact strength	23 °C; 3.2 mm	kJ/m²	based ISO 180-A	**90P**
	Izod notched impact strength	-30 °C; 3.2 mm	kJ/m²	based ISO 180-A	**16C**
C	Puncture maximum force	23 °C	N	ISO 6603-2	**5800**
C	Puncture maximum force	-30 °C	N	ISO 6603-2	**6700**
C	Puncture energy	23 °C	J	ISO 6603-2	**65**
C	Puncture energy	-30 °C	J	ISO 6603-2	**70**
	Ball indentation hardness		N/mm²	ISO 2039-1	**110**
	Thermal properties				
C	Glass transition temperature	10 °C/min	°C	ISO 11357-1,-2	**148**
C	Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	**130**
C	Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	**142**
C	Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	**150**
	Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	**151**
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**
C	Burning behavior UL 94 (1.6 mm)	1.5 mm	Class	UL 94	**HB**
	UL recognition	1.5 mm			**UL**
C	Burning behavior UL 94	3.0 mm	Class	UL 94	**HB**
	UL recognition	3.0 mm			**UL**
	Burning behavior UL 94	6.0 mm	Class	UL 94	**HB**
	UL recognition	6.0 mm			**UL**
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 60335-1	**140**
	Relative temperature index (Tensile strength)	1.5 mm	°C	UL 746 B	**125**
	Relative temperature index (Tensile impact strength)	1.5 mm	°C	UL 746 B	**115**
	Relative temperature index (Electric strength)	1.5 mm	°C	UL 746 B	**125**
	Glow wire test (GWFI)	1.0 mm	°C	IEC 60695-2-12	**850**
	Glow wire test (GWFI)	1.5 mm	°C	IEC 60695-2-12	**850**
	Glow wire test (GWFI)	2.0 mm	°C	IEC 60695-2-12	**850**
	Glow wire test (GWFI)	3.0 mm	°C	IEC 60695-2-12	**900**
	Glow wire test	1.5 mm	°C	based EDF HN60 E.02	**850**
	Glow wire test	3.0 mm	°C	based EDF HN60 E.02	**850**
	Application of flame from small burner	Method K; 2.0 mm	Class	DIN 53438-1,-3	**K1**
	Application of flame from small burner	Method F; 2.0 mm	Class	DIN 53438-1,-3	**F1**
	Incandescent bar test	-	Rating	IEC 60707-BH	**BH2/< 30 mm**
	Burning rate (US-FMVSS)	>=1.0 mm	mm/min	ISO 3795	**passed**
	Flash ignition temperature	Procedure B	°C	ASTM D1929	**470**
	Self ignition temperature	Procedure B	°C	ASTM D1929	**540**

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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Typical Values (continuation)

	Properties	Test Conditions	Units	Standards	Makrolon® 3208
	Electrical properties (23 °C/50 % r.h.)				
C	Relative permittivity	100 Hz	-	IEC 60250	**3.1**
C	Relative permittivity	1 MHz	-	IEC 60250	**3.0**
C	Dissipation factor	100 Hz	10^{-4}	IEC 60250	**5**
C	Dissipation factor	1 MHz	10^{-4}	IEC 60250	**95**
C	Volume resistivity		Ohm·m	IEC 60093	**1E14**
C	Surface resistivity		Ohm	IEC 60093	**1E16**
C	Electric strength	1 mm	kV/mm	IEC 60243-1	**33**
C	Comparative tracking index CTI	Solution A	Rating	IEC 60112	**275**
	Comparative tracking index CTI M	Solution B	Rating	IEC 60112	**125**
	Electrolytic corrosion		Rating	IEC 60426	**A1**
	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 % RH	%	ISO 62	**0.12**
C	Density	-	kg/m³	ISO 1183	**1200**
	Water permeation	23 °C; 85 % RH; 100 µm film	g/(m²·24 h)	ISO 15106-1	**15**
	Gas permeation (Oxygen)	100 µm film	cm³/(m²·24 h·bar)	based ISO 2556	**700**
	Gas permeation (Oxygen)	25.4 µm (1 mil) film	cm³/(m²·24 h·bar)	based ISO 2556	**2760**
	Gas permeation (Nitrogen)	100 µm film	cm³/(m²·24 h·bar)	based ISO 2556	**130**
	Gas permeation (Nitrogen)	25.4 µm (1 mil) film	cm³/(m²·24 h·bar)	based ISO 2556	**510**
	Gas permeation (Carbon dioxide)	100 µm film	cm³/(m²·24 h·bar)	based ISO 2556	**4300**
	Gas permeation (Carbon dioxide)	25.4 µm (1 mil) film	cm³/(m²·24 h·bar)	based ISO 2556	**16900**
	Bulk density	Pellets	kg/m³	ISO 60	**660**
	Material specific properties				
C	Viscosity number	-	cm³/g	ISO 1628-4	**67**
	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	**310**
C	Injection molding-Mold temperature	-	°C	ISO 294	**90**
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.

**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.

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