



# MAKROLON® Rx1805

Product Information

## Polycarbonate Resin

Lipid-Resistant, Radiation-Stabilized Medical Grade

### Description

Makrolon Rx1805 thermoplastic resin is a transparent polycarbonate formulated to provide increased resistance to chemical attack from IV (intravenous) fluid products, such as lipid emulsions. It also takes advantage of proprietary technology to significantly reduce the discoloration associated with gamma radiation sterilization. The resin is available in clear tint (451118) and selected colors.

### Applications

Makrolon Rx1805 polycarbonate offers an outstanding balance of high strength, toughness, clarity, processibility, and bondability for medical device components. In addition, it offers improved resistance to chemicals typically encountered in a hospital or clinical environment, particularly intravenous lipid emulsions (see table below). Typical IV applications include luer fittings, stopcocks, “Y”-site medication ports, tubing connectors, spikes, and other critical components that may be subjected to high stresses while in contact with these chemicals.

### Chemical Compatibility with Lipids\*

Strain Level	Maximum % Elongation Retention	
	Rx1805	Standard Polycarbonate
0%	119	117
1%	119	107
1.4%	115	92
2.5%	104	—
5%	64	—

### Biocompatibility

Makrolon Rx1805 resin is designated as “medical-grade” and has 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.

**Only “medical-grade” products may be considered candidates for applications requiring biocompatibility.**

Regind resins must not be used in medical applications requiring biocompatibility.

### Manufacturer’s Responsibility

It is the responsibility of the medical device, biological product or pharmaceutical manufacturer (“Manufacturer”) to determine the suitability of all component parts and raw materials, including Makrolon Rx1805 polycarbonate, used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood, or other bodily fluids. Under no circumstances may Makrolon Rx1805 resin be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may Makrolon Rx1805 be used in any other bodily implant applications, or any applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days, based on FDA-Modified ISO 10993, Part 1 “Biological Evaluation of Medical Devices” tests.

The suitability of a Bayer resin in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, or external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single-use medical devices made from a Bayer resin are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

\* Test bars were soaked with gauze saturated with a 20% IV fat emulsion for 48 hours at 73° F. Some test bars broke before they could be measured (indicated by a dash in the table).

## Sterilization

Parts molded from Makrolon Rx1805 resin are sterilizable using radiation, ethylene oxide, or steam autoclaving.

When sterilizing with steam, germicides and detergents must be rinsed thoroughly from polycarbonate parts prior to autoclaving. Failure to thoroughly remove germicides and detergents from the part prior to autoclaving may cause accelerated degradation of the polycarbonate.

Steam sterilization temperatures for parts made of Makrolon polycarbonate must not exceed 250°F (121°C) to avoid part deformation. Please note that ***permanent immersion of polycarbonate parts in water above 140°F (60°C) or in steam causes loss of material properties and must be avoided.*** Furthermore, condensed steam should not be allowed to accumulate, as this may cause damage to the parts. Polycarbonate parts should also be protected from damage by substances such as alkaline corrosion inhibitors, which are frequently added to boiler feed water.

The sterilization method and the number of sterilization cycles a part made from Makrolon Rx1805 resin can withstand will vary depending upon type/grade of resin, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

## Drying

All polycarbonate resins are hygroscopic and must be thoroughly dried prior to processing. A desiccant dehumidifying hopper dryer is recommended. To achieve a moisture content of less than 0.02%, hopper inlet air temperature should be 250°F (121°C) and inlet air dew point should be -20°F (-29°C) or lower. The hopper capacity should be sufficient to provide a minimum residence time of 4 hours. Additional information on drying procedures is available in the Bayer brochure *General Drying Guide*.

## Processing

Makrolon Rx1805 resin may be easily processed on commercially available equipment suitable for polycarbonate injection molding. Typical processing parameters are noted at right. Actual processing conditions will depend on machine size, mold design, material residence time, shot size, etc.

### Typical Injection Molding Conditions

Barrel Temperatures:	
Rear .....	465°–510°F (241°–266°C)
Middle .....	515°–550°F (268°–288°C)
Front .....	535°–575°F (279°–302°C)
Nozzle .....	515°–585°F (268°–307°C)
Melt Temperature .....	540°–575°F (282°–302°C)
Mold Temperature .....	150°–220°F (65°–105°C)
Injection Pressure .....	10,000–20,000 psi
Hold Pressure .....	50–70% Injection Pressure
Back Pressure .....	50–100 psi
Screw Speed .....	50–75 rpm
Injection Speed .....	Moderate to Fast
Cushion .....	1/8–1/4 in
Clamp .....	3–5 ton/in <sup>2</sup>

Additional information on processing may be obtained by consulting the Bayer publication *Makrolon Polycarbonate — A Processing Guide for Injection Molding* and by contacting a Bayer technical service representative.

## General Characteristics of Polycarbonate

**Hydrolytic Stability.** Parts molded from polycarbonate absorb only 0.15 to 0.19% water at room temperature and 50% relative humidity. Dimensional stability and mechanical properties remain virtually unaffected. Even with immersion in water, dimensional changes measure only about 0.5%. Although frequent, intermittent contact with hot water does not harm polycarbonate, continuous exposure to humidity or water at high temperatures (>140°F/60°C) is not recommended due to hydrolytic degradation, which reduces impact strength and tensile properties.

**Gas Permeability.** Steam permeability, measured on 100- $\mu$ m thick film, is 15 g/m<sup>2</sup>·24 h (0.97 g/100 in<sup>2</sup>·24 h). Significant permeability also exists for other gases, such as hydrogen, carbon dioxide, sulfur dioxide, helium, ethylene oxide, and oxygen.

**Chemical Resistance.** Polycarbonate is resistant to mineral acids (even in high concentrations), a large number of organic acids, many oxidizing and reducing agents, neutral and acidic saline solutions, some greases and oils, saturated aliphatic and cycloaliphatic hydrocarbons, and most alcohols. It is important to note that polycarbonate is degraded by alkaline solutions, ammonia gas and its solutions, and amines. Polycarbonate dissolves in a number of organic solvents, such as halogenated hydrocarbons and some aromatic hydrocarbons. Other organic compounds cause polycarbonate to swell or stress-crack, e.g., acetone and methyl ethyl ketone. Since chemical resistance to various media is dependent on variables, such as concentration, time, temperature, part design, and residual stresses, the above information should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions prior to commercial use.

Typical Properties* for Clear Tint Resin	ASTM Test Method (Other)	Makrolon® Rx1805 Resin	
		U.S. Conventional	SI Metric
<b>General</b> Specific Gravity Density Specific Volume Mold Shrinkage Water Absorption, Immersion at 73°F (23°C): 24 Hours Equilibrium Melt Flow Rate <sup>a</sup> at 300°C/1.2-kg Load	D 792 D 792 D 792 D 955 D 570  D 1238	1.20  0.043 lb/in <sup>3</sup> 23.1 in <sup>3</sup> /lb 0.006–0.008 in/in	1.20 g/cm <sup>3</sup> 0.83 cm <sup>3</sup> /g 0.006–0.008 mm/mm  0.12% 0.30% 6.5 g/10 min
<b>Optical</b> Transmittance at 0.125-in (3.2-mm) Thickness	D 1003	76%	
<b>Mechanical</b> Tensile Stress at Yield Tensile Stress at Break Tensile Elongation at Yield Tensile Elongation at Break Flexural Stress at 5% Strain Flexural Modulus Impact Strength, Notched Izod: 73°F (23°C) 0.125-in (3.2-mm) Thickness	D 638 D 638 D 638 D 638 D 790 D 790 D 256	9,400 lb/in <sup>2</sup> 10,200 lb/in <sup>2</sup>   13,000 lb/in <sup>2</sup> 340,000 lb/in <sup>2</sup>  18 ft·lb/in	65 MPa 70 MPa 6% 120% 86 MPa 2.4 GPa  960 J/m
<b>Thermal</b> Deflection Temperature, Unannealed: 0.250-in (6.4-mm) Thickness 264-psi (1.82-MPa) Load 66-psi (0.46-MPa) Load Vicat Softening Temperature: 50N; 50K/h	D 648   D 1525	259°F 273°F 291°F	126°C 134°C 144°C

\* These items are provided as general information only. They are approximate values and are not part of the product specifications. Type and quantity of pigments or additives used to obtain certain colors and special effects can affect material properties.

<sup>a</sup> For information on using melt flow as a quality control procedure, see the Bayer publication Makrolon Polycarbonate — A Processing Guide for Injection Molding.

### Regulatory Compliance Information

Some of the end uses of the products described in this bulletin must comply with applicable regulations, such as FDA, NSF, USDA, and CPSC. If you have any questions on the regulatory status of this product, contact your Bayer representative or Bayer's Regulatory Affairs Manager in Pittsburgh, Pa.

### Health and Safety Information

Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling Makrolon Rx1805 resin. Before working with this product, you must read and become familiar with the available information on its hazards, proper use, and handling. This cannot be overemphasized. Information is available in several forms, e.g., material safety data sheets and product labels. Consult your Bayer MaterialScience representative or contact Bayer's Product Safety and Regulatory Affairs Department in Pittsburgh, Pa.

Note: The information contained in this bulletin is current as of December 2002. Please contact Bayer MaterialScience to determine whether this publication has been revised.

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