

Polycarbonate

Grade

Makrolon 2558-1112

Value Plastics Material Code

-9

Manufacturer

Bayer Corporation

Bayer Material Science

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MAKROLON® 2558

Product Information

Polycarbonate Resin

General-Purpose, FDA-Quality Grade

Description

Makrolon 2558 polycarbonate resin is a linear, easy-flow thermoplastic; it is the lowest-viscosity (i.e., highest-melt-flow) grade produced in the Makrolon polycarbonate product line utilizing standard polycarbonate resin technology. It is produced in pellet form for processing primarily by injection molding and contains an internal mold release additive. The resin is available in natural clear, clear tints, and transparent, translucent, and opaque colors.

Makrolon 2558 resin complies with FDA regulation 21 CFR 177.1580 (Polycarbonate Resins) and may be used in contact with all food types. Color possibilities are limited for food-contact applications (i.e., some colors are limited to Conditions of Use B, see FDA regulation 21 CFR 175.300 and 176.170). Please consult your Bayer Corporation representative concerning food-contact applications.

Biocompatibility

Certain color formulations of grade 2558 (clear tint 1112 and colors 3282 and 3291, for example) meet the requirements of the FDA-Modified ISO 10993, Part I "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. *Only these products may be considered as candidates for applications requiring biocompatibility.*

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

Applications

Makrolon 2558 has an excellent balance of engineering properties, including outstanding impact strength and ductility, a large service temperature range, excellent electrical properties, and dimensional stability.

Makrolon 2558 resin offers an improvement in flow and a wider processing window over Makrolon 2658 resin while retaining most of the typical properties. This general-purpose grade is used in various applications in the consumer, industrial, and medical markets. As with any product, use of Makrolon 2558 resin in a given application must be tested (including field testing, etc.) in advance by the user to determine suitability.

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 2558 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, however, may Makrolon 2558 resin 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 I "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.

Sterilization

Parts molded from Makrolon 2558 resin are sterilizable using radiation, ethylene oxide, or steam autoclaving. The sterilization method and the number of sterilization cycles a part made from Makrolon 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 general-purpose polycarbonate resins may be easily processed on commercially available equipment suitable for injection molding of polycarbonate. Typical processing parameters are noted below. 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 (240°–265°C)
Middle	515°–550°F (270°–290°C)
Front	535°–575°F (280°–300°C)
Nozzle	515°–585°F (270°–305°C)
Melt Temperature	540°–575°F (280°–300°C)
Mold Temperature	150°–220°F (65°–105°C)
Injection Pressure	10,000–20,000 psi
Hold Pressure	50–70% of 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 ²

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 Corporation technical service representative.

Regrind Information

Where end-use requirements permit, up to 20% Makrolon resin regrind may be used with virgin material, provided that the material is kept free of contamination and is properly dried (see section on Drying). Any regrind used must be generated from properly molded parts, sprues, and/or runners. All regrind used must be clean, uncontaminated, and thoroughly blended with virgin resin prior to drying and processing. Under no circumstances should degraded, discolored, or contaminated material be used for regrind. Materials of this type should be discarded.

Improperly mixed and/or dried regrind may diminish the desired properties of Makrolon resin. It is critical that you test finished parts produced with any amount of regrind to ensure that your end-use performance requirements are fully met. Regulatory or testing organizations (e.g., UL) may have specific requirements limiting the allowable amount of regrind. Because third party regrind generally does not have a traceable heat history or offer any assurance that proper temperatures, conditions, and/or materials were used in processing, extreme caution must be exercised in buying and using regrind from third parties.

The use of regrind material should be avoided entirely in those applications where resin properties equivalent to virgin material are required, including but not limited to color quality, impact strength, resin purity, and/or load-bearing performance.

Regulatory Compliance Information

Some of the end uses of the products described in this bulletin must comply with applicable regulations, such as the FDA, NSF, USDA, and CPSC. If you have any questions on the regulatory status of these products, contact your Bayer Corporation 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 2558 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 Corporation representative or contact Bayer's Product Safety and Regulatory Affairs Department in Pittsburgh, Pa.

Biocompatibility Testing

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. *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 Class 6 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—atomic absorption (extraction and ash)
- Pyrogen study
- Sensitization (maximization method)—saline extract, oil extract
- Mutagenicity, Ames test—saline extract, oil extract

Test data will be mailed on request. Please see *Medical Contacts* on page 30.

Sterilization

Medical devices typically require sterilization before use. There are three sterilization methods prevalent in the medical industry:

- Heat (both steam autoclave and, to a lesser extent, dry heat)
- Ethylene oxide (EtO) gas
- Irradiation (both gamma and electron beam methods)

The table below shows which Bayer Products are suitable for each sterilization method. However, the sterilization method and the number of sterilization cycles a medical device made from a Bayer Product can withstand will vary depending upon the type/grade of Product, 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.

Parts molded or extruded from Texin resins are sterilizable using ethylene oxide, radiation or dry heat. Parts made of Texin resins must not be sterilized using steam autoclaving or boiling water techniques. Furthermore, these sterilization methods must not be used with aromatic grades of Texin resin because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

Acceptable Sterilization Methods for Bayer Medical Products*

	Ethylene Oxide Sterilization	Gamma Radiation	Electron Beam Radiation	Steam Autoclave	High-Heat Steam Autoclave
Makrolon PC	Yes	Yes	Yes	Yes**	No
Apec High-Heat PC	Yes	Yes	Yes	Yes**	Yes**
Makrofol PC Film	Yes	Yes	Yes	Yes**	No
Makroblend PC/PET	Yes	Yes	Yes	Yes**	No
Bayblend PC/ABS	Yes	Yes	Yes	No	No
Lustran ABS	Yes	Yes	Yes	No	No
Lustran SAN	Yes	Yes	Yes	No	No
Durethan PA	Yes	Yes	Yes	No	No
Texin TPU	Yes	Yes	Yes	No	No

* The suitability of a specific grade of a Bayer product for a particular sterilization method must be evaluated by the Manufacturer as described above.

** Refer to guidelines in Autoclaving (Saturated Steam Sterilization) on page 9.

Sterilization *continued*

Autoclaving (Saturated Steam Sterilization)

Several Bayer thermoplastic products are suitable for applications that undergo steam sterilization under standard autoclaving conditions, i.e., 250°F (121°C) for 15 to 30 minutes. These products include Makrolon polycarbonate, Apec high-heat polycarbonate, Makrofol polycarbonate film, and Makroblend polycarbonate/PET blend. The number of allowable sterilization cycles must be evaluated and determined by the Manufacturer (see sterilization guidelines on page 8).

Sterilization temperatures for parts made of Makrolon polycarbonate (as well as Makrofol PC film and Makroblend PC/PET blend) must not exceed 250°F (121°C) to avoid part deformation. Parts made of Apec high-heat polycarbonate, however, may be subjected to sterilization temperatures up to 275°F (135°C), thus reducing the amount of time needed for sterilization.

It is necessary to thoroughly rinse germicides and detergents from parts made from polycarbonate prior to autoclaving. Failure to thoroughly remove germicides and detergents from the part prior to autoclaving may cause accelerated degradation of the polycarbonate.

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 also cause damage to the parts. Parts made from polycarbonate should also be protected from damage by substances such as alkaline corrosion inhibitors, which are frequently added to boiler feed water.

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 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, however, may any Bayer Product be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may any Bayer Product 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. Furthermore, for aromatic grades of Texin resins, such longer-term uses are not permissible also because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

The suitability of a Bayer Product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, processing parameters, 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 Product 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.



Bayer MaterialScience

February 22, 2005

Mr. Bob Corley
Modified Plastics and Color Science
Email: bcorley@modifiedplastics.com

Re: Makrolon 2558 550115 (formerly Makrolon 2558 1112)
Makrolon 2458 550115 (formerly Makrolon 2458 1112)

Bayer MaterialScience LLC
Product Safety & Regulatory Affairs
100 Bayer Road
Pittsburgh PA 15205 9741
Phone: 412 777 3491
FAX: 412 777 7484
e-mail: don.naragon@bayermaterialscience.com

Dear Mr. Corley

Responding to your request, Makrolon 2558 550115 (formerly Makrolon 2558 1112) and Makrolon 2458 550115 (formerly Makrolon 2458 1112) are synthetic organic chemicals that may contain materials that are derived from tallow sources. Our suppliers of these tallow derivative products have assured us that only U.S. and Canadian sources of tallow are used to manufacture these materials.

In an interim final rule published in the July 14, '04 Federal Register the FDA stated in 21 CFR 189.5(b) "No human food shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials." However, in 189.5(a)(1) the FDA stated "Prohibited cattle materials do not include . . . tallow derivatives."

Thank you for your interest in Bayer products.

Sincerely, . . .

Donald D. Naragon, Ph.D.
Principal Scientist, Regulatory Affairs

DDN:sah

**Bayer Polymers
Americas**



November 17, 2004

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As communicated in July 2001, Bayer is implementing a new global color numbering system across our thermoplastic product lines effective September 1, 2001. This is a color nomenclature change only, and the color formulations will remain the same. The change is intended to improve our working relationship with you by unifying our colors worldwide.

Below is a listing that provides a cross reference between the old and new color codes:

Old Color Code	New Color Code
1112	550115
1118	451118

Bayer is committed to making this transition as seamless as possible for our customers. Bayer will display both the old and new color designations on Bayer documents and container labels for two years. You may continue to order as you currently do during the near-term, however we ask that you change your internal systems to reflect the new color numbers as soon as possible.

Products labeled after September 1st will show the new color number first while also referencing the old color number. You may, for sometime, receive material showing only the old color number as that material was produced prior to this change. We appreciate your patience during the transition period.

If you have questions about this change, please let me know.

Sincerely,

Jack Chan

Technical Marketing Specialist



Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-8741
Phone: 412 777-2000

October 8, 1996

Bruce Williams
Valve Plastics Inc.
3325 Timberline Road
Fort Collins, CO 80525

FAX: 970-223-0953

Dear Mr. Williams:

As requested, we are providing you with the following information on our product Makrolon 2558-1112.

Makrolon 2558-1112 itself was not tested, however Makrolon 2458-EX03/EX04 were tested for ISO 10993-1 bio-compatibility. The base polycarbonate resin used in this product is identical to Makrolon 2458-EX03/EX04. Makrolon 2458-EX03/EX04 were formulated to contain higher levels of the colorants and additives than used in commercial grades of polycarbonates.

The formula for Makrolon 2558-1112 used only colorants and additives which were included in the tested products. Since these products met the testing requirements with higher levels than the commercial loading, it is expected that Makrolon 2558-1112 would also met the requirements.

Makrolon 2458-EX03/EX04 met the USP 23 Plastics Class VI and ISO 10993-1 testing requirements. Prior to testing, the sample plaques were sterilized by Gamma at 3.2 Mrad Dosage and ethylene oxide. Tests conducted in accordance with "Good Laboratory Practice" include:

1. Acute Systemic Toxicity
2. Intracutaneous Toxicity
3. Muscle Implantation Test
4. Cytotoxicity - MEM Elution
5. Hemolysis - Extraction and Direct
6. Physico-Chemical Tests
7. Heavy Metal Analysis - Atomic Abs.(Ext.) Purified Water & Saline
8. Heavy Metal Analysis - Atomic Abs.(Ash)
9. Pyrogen Study
10. Sensitization (Maximization Method) Saline & Cottonseed Oil Extract
11. Mutagenicity, Ames Test - Ethanol & Saline