Developmental Product

Bayer MaterialScience

Product Information

MAKROBLEND® DP4-1386

Polycarbonate/Polyester Blend

Transparent Grade

Description

Makroblend DP4-1386 resin is a transparent blend of Makrolon® polycarbonate and polyester with good radiation resistance and good chemical resistance. As with any product, use of Makroblend DP4-1386 resin in a given application must be tested (including but not limited to field testing) in advance by the user to determine suitability.

Medical Applications

Makroblend DP4-1386 resin is suitable for use in various medical devices. Typical medical applications include connectors, pumps, housings and reservoirs.

Biocompatibility: Certain color formulations of Makroblend DP4-1386 resin, (such as clear tint 550197) meet 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 products that meet these requirements may be considered candidates for applications requiring biocompatibility.

Regrind 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 Makroblend DP4-1386 resin, 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 Makroblend DP4-1386 resin be used in any cosmetic, reconstructive or reproductive implant applications. Nor may Makroblend DP4-1386 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 1 "Biological Evaluation of Medical Devices" tests.

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, residual stresses, and 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.

Sterilization: Parts molded from Makroblend DP4-1386 resin are sterilizable using radiation, ethylene oxide, or steam autoclaving. When sterilizing with steam, germicides and detergents must be rinsed thoroughly from Makroblend 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 Makroblend DP4-1386 resin must not exceed 250º F (121ºC) to avoid part deformation. Please note that permanent immersion of Makroblend parts in water above 140ºF (60ºC) 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 parts.

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Makroblend 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 medical device made from Makroblend DP4-1386 resin can withstand will vary depending upon 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

Drying the resin before processing is essential to optimize property performance and appearance in molded parts. A desiccant dehumidifying hopper dryer is recommended. To achieve a moisture content ≤0.01%, inlet air temperature should be 220°– 230°F (104°– 110°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 4–6 hours. Total drying time should not exceed 36 hours. Additional information on drying may be found in the Bayer brochure *General Drying Guide*.

Processing

Makroblend DP4-1386 resin can be processed on commercially available equipment for injection molding. Typical molding conditions 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	470° - 490°F (243° - 254°C)
Middle	475° - 495°F (246° - 257°C)
Front	480° - 500°F (249° - 260°C)
Nozzle	485° - 505°F (252° - 263°C)
Melt Temperature	500° - 525°F (260° - 274°C)
Mold Temperature	65° - 150°F (18° - 66°C)
Injection Pressure	10,000 – 20,000 psi
Hold Pressure	50 – 75% of Injection Pressure
Back Pressure	50 – 100 psi
Screw Speed	40 – 70 rpm
Injection Speed	Slow to Moderate
Cushion	1/8 – 1/4 in
Clamp	3 – 5 ton/in^2

Additional Information on processing may be obtained by consulting the Bayer publication *Makroblend Polycarbonate Blend – Injection Molding Guidelines* and by contacting a Bayer MaterialScience technical service representative.

Regrind Usage

Where end-use requirements permit, up to 20% Makroblend 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 properly discarded.

Improperly mixed and/or dried regrind may diminish the desired properties of Makroblend 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.

Developmental Product Information

Makroblend DP4-1386 resin is a developmental product and is not considered part of the Bayer MaterialScience line of standard commercial products. Complete commercialization and continued supply are not assured. The purchaser/ user agrees that Bayer MaterialScience reserves the right to discontinue this product without prior notice.

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Makroblend® DP4-1386 Resin U.S. Conventional	SI Metric
General			
Specific Gravity	D 792	1.20	
Density	D 792	0.043 lb/in³	1.20 g/cm³
Specific Volume	D 792	23.1 in³/lb	0.83 cm³/g
Mold Shrinkage	D 955	0.006–0.008 in/in	0.006–0.008 mm/mm
Water Absorption, Immersion at 73°F (23°C):	D 570		
Equilibrium		0.17%	
Melt Flow Rate[a] at 265°C/5-kg Load	D 1238	15–20 g/10 min	
Spiral Flow Length, 0.100-in (2.54-mm) Thickness:	(Bayer)		
510°F (266°C) Melt Temperature		16 in	41 cm
Optical			
Transmittance at 0.100-in (2.54-mm) Thickness	D 1003	87%	
Haze at 0.100-in (2.54-mm) Thickness	D 1003	0.5%	
Mechanical			
Tensile Stress at Yield	D 638	8,900 lb/in²	61 MPa
Tensile Stress at Break	D 638	8,700 lb/in²	60 MPa
Tensile Elongation at Yield	D 638	5%	
Tensile Elongation at Break	D 638	110%	
Flexural Stress at 5% Strain	D 790	12,000 lb/in²	83 MPa
Flexural Modulus	D 790	330,000 lb/in²	2.3 GPa
Impact Strength, Notched Izod:	D 256		
0.100-in (2.54-mm) Thickness			
73°F (23°C)		15 ft lb/in	801 J/m
Instrumented Impact, Total Energy:[b]	D 3763		
73°F (23°C)		51 ft lb	69J
-20°F (-29°C)		51 ft lb	69J
-40°F (-40°C)		51 ft lb	69J
Rockwell Hardness, R Scale	D 785	124	
Thermal			
Deflection Temperature, Unannealed:	D 648		
0.250-in (6.4-mm) Thickness			
264-psi (1.82-MPa) Load		220°F	104°C
66-psi (0.46-MPa) Load		240°F	116°C
Relative Temperature Index:	(UL746B)		
1.5-mm (0.059-in) Thickness			
Electrical		95°C	
Mechanical with Impact		85°C	
Mechanical without Impact		90°C	
Flammability**			
UL94 Flame Class	(UL94)		
1.5 mm (0.059-in) Thickness		HB Rating	
3.0 mm (0.118-in) Thickness		HB Rating	

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***Flammability results are based on small-scale laboratory tests for purposes of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.*
[a] For information on using melt flow as a quality control procedure, see the Bayer publication Makroblend Polycarbonate Blend — Injection Molding Guidelines.
[b] 0.125-in thickness, 0.5-in dart, 3-in clamp, 15 mph