Bayer MaterialScience

APEC® 1745

Product Information

High-Heat Polycarbonate Resin

Medical Grade

Description

Apec 1745 high-heat polycarbonate is an amorphous, naturally transparent thermoplastic for processing by injection molding. It is part of a new generation of aromatic copolycarbonates which extend the service range of standard polycarbonate towards higher temperatures. As such, Apec 1745 resin offers the strength and optical properties associated with Makrolon® polycarbonate together with higher heat deflection temperatures. Apec 1745 is a release grade. It is available in natural clear and selected colors.

Applications

Apec 1745 resin offers an excellent combination of high heat resistance, clarity, and processibility. Typical applications include medical devices, dental and surgical instruments, and laboratory equipment. As with any product, use of Apec 1745 resin in a given application must be tested (including but not limited to field testing) in advance by the user to determine suitability.

General Characteristics of Apec High-Heat Polycarbonate

Hydrolytic Stability. Parts molded from polycarbonate absorb only about 0.15% 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 and tensile properties.

Chemical Resistance. The behavior of Apec high-heat polycarbonate in contact with chemicals is similar to that of standard polycarbonate. Apec resins are resistant to mineral acids, 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 Apec polycarbonate is degraded by alkaline solutions, ammonia gas and its solutions, and amines. Apec polycarbonate dissolves in a number of organic solvents, such as halogenated hydrocarbons and specific non-halogenated solvents such as toluene, ethylacetate, methyl acetate, methyl ethyl ketone and tetrahydrofuran. The solubility of Apec resins is grade-dependant. Special high purity solubility grades are available for solution applications. Other organic compounds cause polycarbonate to swell or stress-crack, e.g., acetone. 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 applications prior to commercial use.

Biocompatibility

Apec 1745 resin is designated as "medical-grade" and has met 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 medical-grade resins may be considered candidates for applications requiring biocompatibility.*

Regrind 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 Apec 1745 polycarbonate 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, however, may Apec 1745 resin be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may Apec 1745 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 Apec 1745 resin are sterilizable using radiation, ethylene oxide, or steam autoclaving. When sterilizing with steam, germicides and detergents must be rinsed thoroughly from parts molded from Apec resin prior to autoclaving. Failure to thoroughly remove germicides and detergents from the part prior to autoclaving may cause accelerated degradation of the Apec resin. Parts molded from Apec resin should also be protected from damage by substances such as alkaline corrosion inhibitors, which are frequently added to boiler feed water. In contrast to standard autoclaving conditions, i.e., 250°F (121°C) for 15 to 30 minutes, parts made of Apec high-heat polycarbonate may be subjected to sterilization temperatures up to 275°F (135°C), thus reducing the amount of time needed for sterilization. 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.

The sterilization method and the number of sterilization cycles a part made from Apec 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 265°F (130°C) and inlet air dew point should be 0°F (-18°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

Apec 1745 resin can be processed on commercially available equipment suitable for injection molding of polycarbonate. Generally, appropriate processing conditions are very similar to those used for standard polycarbonate, with the exception that a higher melt temperature is required due to the higher melt viscosity of Apec high-heat polycarbonate.

Typically, nozzles used for processing Apec resin should have larger internal diameters than those used for standard polycarbonate. Injection speed and holding pressure should be kept low. Annealing of parts molded from Apec resin is not normally required. If the molding cycle is interrupted, the cylinder temperatures should be reduced to avoid material degradation.

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	590°–610°F (310°–321°C)
Middle	595°–615°F (313°–324°C)
Front	600°–620°F (316°–327°C)
Nozzle	590°–610°F (310°–321°C)
Melt Temperature	590°–630°F (310°–332°C)
Mold Temperature	175°–250°F (79°–121°C)
Injection Pressure	15,000–20,000 psi
Hold Pressure	40–60% Injection Pressure
Back Pressure	75 psi
Screw Speed	75 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 *Apec High-Heat Polycarbonate — Injection Molding Guidelines* and by contacting a Bayer MaterialScience LLC technical service representative.

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Apec® 1745[a] Resin Conventional U.S.	Metric SI
General			
Specific Gravity	D 792	1.17	
Density	D 792	0.042 lb/in^3	1.17 g/cm^3
Specific Volume	D 792	23.7 in^3/lb	0.85 cm^3/g
Mold Shrinkage	D 955	0.8%	
Water Absorption, Immersion at 73°F (23°C):	D 570		
24 Hours		0.2%	
Saturation		0.4%	
Melt Flow Rate[b] at 330°C/2.16-kg Load	D 1238	15 g/10 min	
Optical			
Transmittance at 0.125-in (3.2-mm) Thickness	D 1003	88%	
Haze at 0.125-in (3.2-mm) Thickness	D 1003	1%	
Refractive Index	D 542	1.578	
Mechanical[c]			
Tensile Stress at Yield	D 638	9,400 lb/in^2	65 MPa
Tensile Elongation at Yield	D 638	7%	
Tensile Elongation at Break	D 638	>50%	
Tensile Modulus (1mm/min)	D 638	330,000 lb/in^2	2.3 GPa
Flexural Stress at 5% Strain	D 790	12,500 lb/in^2	86 MPa
Flexural Modulus	D 790	320,000 lb/in^2	2.2 GPa
Impact Strength:			
0.125-in (3.2-mm) Thickness			
Notched Izod, 73°F (23°C)	D 256	6 ft·lb/in	320 J/m
Unnotched, 73°F (23°C)	D 4812	No Break	
Unnotched, -40°F (-40°C)	D 4812	No Break	
Thermal			
Deflection Temperature, Unannealed:	D 648		
0.250-in (6.4-mm) Thickness			
264-psi (1.82-MPa) Load		302°F	150°C
66-psi (0.46-MPa) Load		324°F	162°C
Coefficient of Linear Thermal Expansion	D 696	3.9 E-05 in/in/°F	7.0 E-05 mm/mm/°C
Vicat Softening Temperature, 50N; 120K/h	D 1525	342°F	172°C
Electrical			
Volume Resistivity (Tinfoil Electrodes)	D 257	>1.0 E+16 ohm·cm	
Surface Resistivity	D 257	>1.0 E+16 ohm	
Dielectric Strength (Short Time under Oil at 73°F [23°C] and 0.125-in [3.2-mm] Thickness)	D 149	>400 V/mil	>16 kV/mm
Dielectric Constant (Tinfoil Electrodes): 60 Hz	D 150	2.9	
1 MHz		2.9	
Dissipation Factor (Tinfoil Electrodes): 60 Hz	D 150	0.001	
1 MHz		0.01	

** These items are provided as general information only. They are approximate values and are not part of the product specifications.*

[a] *Formerly Apec DP9-9340R.*

[b] *For information on using melt flow as a quality control procedure, see the Bayer publication* Apec High-Heat Polycarbonate — Injection Molding Guidelines.

[c] *Type and quantity of pigment used in opaque colors can affect mechanical properties, especially toughness.*

Regulatory Compliance Information

Some of the end uses of the product 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 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 Apec 1745 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 LLC 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 August 2001. Please contact Bayer MaterialScience LLC to determine whether this publication has been revised.

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