Bayer MaterialScience

Product Information

TEXIN® RxT85A

Thermoplastic Polyurethane

Aromatic Polyether-Based Grade

Description and Applications

Texin RxT85A resin is an aromatic polyether-based thermoplastic polyurethane. It can be processed by injection molding, extrusion or blow molding. Texin RxT85A offers outstanding abrasion resistance, impact strength, toughness and flexibility. It also exhibits excellent hydrolytic stability.

Typical medical applications include anesthetic connectors, catheters, flexible tubing, film, seals and gaskets and extruded profiles.

Medical Applications

Biocompatibility: Texin RxT85A resin meets 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 virgin Texin RxT85A resin has been tested according to certain tests under ISO 10993-1. Any use of regrind must be evaluated by the medical device manufacturer for 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 Texin RxT85A 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. Texin RxT85A resin shall not be considered a candidate for the following types of medical applications without the explicit written agreement of Bayer: (a) any bodily implant application; (b) applications involving contact with or storage of human tissue, blood or other bodily fluids for greater than 30 days; or (c) applications involving external communicating devices having greater than 24 hour contact with patients.

Over time, polyurethane materials may hydrolyze to their corresponding precursor diamines (for example, aromatic polyurethanes based on diphenylmethane diisocyanate (MDI) may hydrolyze and produce methylene dianiline (MDA)). This condition needs to be considered in any end-use application.

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.

Bayer does not warrant or represent that medical devices made from a Bayer product aresuitable 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 or extruded from Texin RxT85A resin can be sterilized using ethylene oxide, radiation or dry heat.

The use of steam autoclaving or boiling water sterilization techniques may hydrolyze polyurethane materials to their corresponding precursor diamines (for example, aromatic polyurethanes based on diphenylmethane diisocyanate (MDI) may hydrolyze and produce methylene dianiline (MDA)). This condition needs to be considered by the device manufacturer in defining sterilization conditions.

The sterilization method and the number of sterilization cycles a medical device made from Texin RxT85A resin can withstand will vary depending upon 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.

Storage and Drying

Texin thermoplastic polyurethane resins are hygroscopic and will absorb ambient moisture. The resins should remain in their sealed containers and stored in a dry area. Storage temperatures should not exceed 86°F (30°C). Unused resin from opened containers, or reground material that is not to be used immediately should also be stored in sealed containers under cool and dry conditions.

Prior to processing, Texin RxT85A resin must be thoroughly dried for a minimum of 2 hours in a desiccant dehumidifying hopper dryer to a moisture content of less than 0.03%. Hopper inlet air temperature should be 200-220°F (93-104°C), the inlet air dew point should be 0°F (-20°C) or lower.

Injection Molding, Extrusion and Blow Molding Conditions

Typical starting conditions for injection molding, extrusion, and blow molding are noted below. It is recommended that initial processing is done at the lower end of the suggested temperature ranges and increased as necessary. Actual processing conditions will depend on machine size, mold design, material residence time, shot size, part geometry, etc.

Typical Injection Molding Conditions

Barrel Temperatures:	
Rear	380º-400ºF (193º-204ºC)
Middle	385º-405ºF (196º-207ºC)
Front	385º-405ºF (196º-207ºC)
Nozzle	390º-410ºF (199º-210ºC)
Melt Temperature	390º-410ºF (199º-210ºC)
Mold Temperature	60º-100ºF (16º-38ºC)
Injection Pressure	6,000-15,000 psi
Hold Pressure	60-80% of Injection Pressure
Back Pressure	800 psi max.
Screw Speed	40-80 rpm
Injection Speed	Moderate
Cushion	1/8 inch max

Typical Temperature Profile for Extrusion and Blow Molding

Rear (Feed)	360º - 380ºF (182º - 193ºC)
Middle (Transition)	380º - 400ºF (193º - 204ºC)
Front (Meter)	380º - 400ºF (193º - 204ºC)
Die	380º - 410ºF (193º - 210ºC)
Melt	390º - 410ºF (199º - 210ºC)

Regulatory Compliance Information

The end uses of the product described in this bulletin must comply with applicable regulations, such as the FDA. If you have any questions on the regulatory status of these products, contact your Bayer Material Science 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 Texin RxT85A 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 Material Science representative or contact Bayer's Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

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

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Units		Texin RxT85A	
		U. S. Conventional	SI Metric	U. S. Conventional	SI Metric
General					
Specific Gravity	D 792 (ISO 1183)			1.12	
Shore Hardness	D 2240 (ISO 868)	A Scale		85A	
Melt Flow Index, typical value	D 1238 (ISO 1193)				
190°C/8.7kg		g/10min		4	
Yellowness Index	E 313 (DIN 6167)			<10	
Taber Abrasion	D 3489 (ISO 4649)				
H-18 wheel, 1000-g load, 1000 cycles		mg Loss		30	
Mold Shrinkage at 100-mil Thickness:	D 955 (ISO 2577)				
Flow Direction		in/in (mm/mm)		0.008	
Cross-Flow Direction		in/in (mm/mm)		0.008	
Mechanical					
Tensile Strength	D 412 (ISO 37)	lb/in^2	MPa	5,300	36.6
Tensile Stress at 100 % Elongation	D 412 (ISO 37)	lb/in^2	MPa	800	5.5
Tensile Stress at 300 % Elongation	D 412 (ISO 37)	lb/in^2	MPa	1,400	9.7
Ultimate Elongation	D 412 (ISO 37)	%		610	
Tear Strength, Die "C"	D 624 (ISO 34)	lbf/in	kN/m	500	87.6
Flexural Modulus	D 790 (ISO 178)				
73ºF (23ºC)		lb/in^2	MPa	3,900	26.9
Compression Set (Post-cured**):	D 395B (ISO 815)				
22 hours at 158ºF (70ºC)		%		40	
22 hours at 73ºF (23ºC)		%		16	
Thermal					
Vicat Softening Temperature (Rate A)	D 1525 (ISO 306)	ºF	ºC	176	80

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***Post-cured for 16 hours at 230ºF (110ºC).*