Texin® RxT50D

Characterization	Texin RxT50D resin is an aromatic polyether-based thermoplastic polyurethane. It can be processed by injection molding, extrusion or blow molding.
Properties / Applications	Texin RxT50D 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. As with any product, use of Texin RxT50D 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	*Biocompatibility:* Texin RxT50D 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 RxT50D 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 RxT50D 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 RxT50D resin shall not be considered a candidate for the following types of medical applications without the explicit written agreement of Covestro: (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 Covestro 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.

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Covestro does not warrant or represent that medical devices made from a Covestro product are 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 or extruded from Texin RxT50D 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 RxT50D 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 RxT50D 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.

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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 be 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 Temperature: Rear	385º-405ºF (196º-207ºC)
Barrel Temperature: Middle	390º-410ºF (199º-210ºC)
Barrel Temperature: Front	390º-410ºF (199º-210ºC)
Barrel Temperature: Nozzle	395º-415ºF (202º-213ºC)
Melt Temperature	395º-415ºF (202º-213ºC)
Mold Temperature	60°–100°F (16°–38°C)
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 in max

Extrusion and Blow Molding Profile

Typical Temperature Profile for Extrusion and Blow Molding

Rear (Feed)	360° - 385°F (182° - 196°C)
Middle (Transition)	380º - 405ºF (193º - 207ºC)
Front (Meter)	380º - 405ºF (193º - 207ºC)
Die	380º - 415ºF (193º - 213ºC)
Melt	390º - 415ºF (199º - 213ºC)

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Typical Properties* for Natural Resin

Property	ASTM Test Method (Other)	Texin RxT50D Resin U.S. Units	Texin RxT50D Resin S.I. Units
General			
Specific Gravity	D 792 (ISO 1183)	1.15	1.15
Shore Hardness	D 2240 (ISO 868)	50D	50D
Melt Flow Index, typical value 200°C/8.7kg	D1238 (ISO 1193)	5g/10min	5g/10min
Yellowness Index	E 313 (DIN 6167)	< 10	< 10
Taber Abrasion: H-18, 1,000-g Load, 1,000 Cycles	D 3489 (ISO 4649)	75 mg Loss	75 mg Loss
Mold Shrinkage, 100-mil thickness: Flow Direction Cross-flow Direction	D 955 (ISO 2577)	0.008 in/in (mm/mm) 0.008 in/in (mm/mm)	0.008 in/in (mm/mm) 0.008 in/in (mm/mm)
Mechanical			
Tensile Strength	D 412 (ISO 37)	7,100 lb/in^2	49.0 MPa
Tensile Stress at 100% Elongation	D 412 (ISO 37)	2,100 lb/in^2	14.5 MPa
Tensile Stress at 300% Elongation	D 412 (ISO 37)	4,000 lb/in^2	27.6 MPa
Ultimate Elongation	D 412 (ISO 37)	480%	480%
Flexural Modulus: 73°F (23°C)	D 790 (ISO 178)	16,500 lb/in^2	113.8 MPa
Tear Strength, Die C	D 624 (ISO 34)	750 lbf/in	131.3 kN/m
Compression Set (postcured):[a] 22 Hours at 158°F (70°C) 22 Hours at 73°F (23°C)	D 395-B (ISO 815)	40% 15%	40% 15%
Thermal			
Vicat Softening Temperature, Rate A	D 1525 (ISO 306)	262°F	128°C

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

a Postcured for 16 hours at 230°F (110°C).

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Health and Safety Information	Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling this product. Before working with this product, you must read and become familiar with the available information on its risks, proper use, and handling. This cannot be overemphasized. Information is available in several forms, e.g., safety data sheets and product labels. For further information contact your Covestro LLC representative or the Product Safety and Regulatory Affairs Department in Pittsburgh, PA.
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 Covestro representative or the Regulatory Affairs Manager in Pittsburgh, PA.

The manner in which you use and the purpose to which you put and utilize our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you utilize our products, technical assistance and information to determine to your own satisfaction whether our products, technical assistance and information are suitable for your intended uses and applications. This application-specific analysis must at least include testing to determine suitability from a technical as well as health, safety, and environmental standpoint. Such testing has not necessarily been done by us. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance, and information. Any statement or recommendation not contained herein is unauthorized and shall not bind us. Nothing herein shall be construed as a recommendation to use any product in conflict with any claim of any patent relative to any material or its use. No license is implied or in fact granted under the claims of any patent.

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Product Datasheet