# Texin® RxT70A

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| **Characterization** | Texin RxT70A resin is an aromatic polyether-based thermoplastic polyurethane. It can be processed by injection molding or extrusion. |
| **Properties / Applications** | Texin RxT70A is characterized by very good hydrolysis, good low temperature flexibility, resiliency and impact strength, high moisture vapor transmission rates and is plasticizer free. Typical medical applications include catheters and catheter balloons, specialty tubing and profiles, connectors, and soft overmolding applications. As with any product, the use of Texin RxT70A 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 RxT70A 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.<br><br>Only virgin Texin RxT70A 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.<br><br>*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 RxT70A 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 RxT70A 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.<br><br>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 RxT70A 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 RxT70A 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 RxT70A 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 180-200°F (82-93°C), the inlet air dew point should be 0°F (-20°C) or lower.



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## Injection Molding and Extrusion Conditions

Typical starting conditions for injection molding and extrusion are noted below. Actual processing conditions will depend on machine size, mold design, material residence time, shot size, part geometry, etc.

### Typical Injection Molding Conditions

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|---|---|
| Barrel Temperature: Rear | 360º-380ºF (182º-193ºC) |
| Barrel Temperature: Middle | 370º-390ºF (188º-199ºC) |
| Barrel Temperature: Front | 370º-390ºF (188º-199ºC) |
| Barrel Temperature: Nozzle | 375º-395ºF (191º-202ºC) |
| Melt Temperature | 370º-390ºF (188º-199ºC) |
| Mold Temperature | 60°–100°F (16°–38°C) |
| Injection Pressure | 6,000 - 15,000 psi |
| Hold Pressure | 60 - 80% of Injection Pressure |
| Back Pressure | 200 psi max. |
| Screw Speed | 40 - 80 rpm |
| Injection Speed | Slow to Moderate |
| Cushion | 1/8 in |

## Extrusion Profile

### Typical Temperature Profile for Extrusion

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|---|---|
| Rear (Feed) | 360° - 390°F (182° - 199°C) |
| Middle (Transition) | 360º - 400ºF (182º - 204ºC) |
| Front (Meter) | 360º - 400ºF (182º - 204ºC) |
| Die | 370º - 400ºF (188º - 204ºC) |
| Melt | 375º - 400ºF (191º - 204ºC) |



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**Typical Properties* for Natural Resin**

| Property | ASTM Test Method (Other) | Texin RxT70A Resin U.S. Units | Texin RxT70A Resin S.I. Units |
|---|---|---|---|
| **General** | | | |
| Specific Gravity | D 792 (ISO 1183) | 1.07 | 1.07 |
| Shore Hardness | D 2240 (ISO 868) | 70A | 70A |
| Melt Flow Index, typical value 200°C/10kg | D1238 (ISO 1193) | 32 g/10min | 32 g/10min |
| Yellowness Index | E 313 (DIN 6167) | < 15 | < 15 |
| Taber Abrasion: H-18, 1,000-g Load, 1,000 Cycles | D 3489 (ISO 4649) | 7 mg Loss | 7 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) | 3,700 lb/in$^2$ | 25.5 MPa |
| Tensile Stress at 100% Elongation | D 412 (ISO 37) | 500 lb/in$^2$ | 3.4 MPa |
| Tensile Stress at 300% Elongation | D 412 (ISO 37) | 750 lb/in$^2$ | 5.2 MPa |
| Ultimate Elongation | D 412 (ISO 37) | 770% | 770% |
| Flexural Modulus: 73°F (23°C) | D 790 (ISO 178) | 2,100 lb/in$^2$ | 14.5 MPa |
| Tear Strength, Die C | D 624 (ISO 34) | 345 lbf/in | 60.5 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) | 30% 11% | 30% 11% |
| **Thermal** | | | |
| Vicat Softening Temperature, Rate A | D 1525 (ISO 306) | 167°F | 75°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 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**