TEXIN® RxS285

Characterization	Texin RxS285 resin is an aromatic polyester-based thermoplastic polyurethane. It can be processed by injection molding, extrusion or blow molding.
Properties / Applications	Texin RxS285 offers outstanding abrasion resistance, impact strength, toughness and flexibility. Typical medical applications include dental ligature, tubing and luers. As with any product, the use of Texin RxS285 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 RxS285 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 RxS285 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 RxS285 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 RxS285 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.

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 TexinRxS285 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 RxS285 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 RxS285 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 180-210°F (82-99°C), the inlet air dew point should be 0°F (-18°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 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 Temperature: Rear	360º-390ºF (182º-199ºC)
Barrel Temperature: Middle	360º-400ºF (182º-204ºC)
Barrel Temperature: Front	360º-410ºF (182º-210ºC)
Barrel Temperature: Nozzle	370º-415ºF (188º-213ºC)
Melt Temperature	385º-405ºF (196º-207ºC)
Mold Temperature	60°–110°F (16°–43°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	Slow to Moderate
Cushion	1/8 in max

Extrusion and Blow Molding Profile

Typical Temperature Profile for Extrusion and Blow Molding

Rear (Feed)	360° - 390°F (182° - 199°C)
Middle (Transition)	360º - 400ºF (182º - 204ºC)
Front (Meter)	360º - 410ºF (182º - 210ºC)
Die	370º - 410ºF (188º - 210ºC)
Melt	375º - 400ºF (191º - 204ºC)

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Typical Properties* for Natural Resin

Property	ASTM Test Method (Other)	Texin RxS285 Resin U.S. Units	Texin RxS285 Resin S.I. Units
General			
Specific Gravity	D 792 (ISO 1183)	1.202	1.202
Shore Hardness	D 2240 (ISO 868)	85A	85A
Melt Flow Index, typical value 190°C/8.7kg	D1238 (ISO 1193)	4 g/10min	4 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)	35 mg Loss	35 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)	5,500 lb/in^2	37.9 MPa
Tensile Stress at 100% Elongation	D 412 (ISO 37)	775 lb/in^2	5.34 MPa
Tensile Stress at 300% Elongation	D 412 (ISO 37)	1,900 lb/in^2	13.1 MPa
Ultimate Elongation	D 412 (ISO 37)	500%	500%
Flexural Modulus: 73°F (23°C)	D 790 (ISO 178)	4,000 lb/in^2	27.6 MPa
Tear Strength, Die C	D 624 (ISO 34)	500 lbf/in	87.6 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)	35% 12%	35% 12%
Thermal			
Vicat Softening Temperature, Rate A	D 1525 (ISO 306)	196°F	91°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.