

DURETHAN[®] T 40

Amorphous Polyamide
Transparent Medical Grade

ISO: 1874-PA61, MT, 12-030

Description

Durethan[®] T 40 amorphous polyamide resin is synthesized through the polycondensation of aliphatic and aromatic monomers and is characterized by its transparency, even in the case of heavy wall thickness. It is suitable for both injection molding and extrusion.

Applications

Durethan[®] T 40 resin can be used in applications which require transparency, good mechanical and electrical properties, and excellent chemical resistance. Durethan[®] T 40 resin may be suitable for fluid reservoirs; housing for filters, valves, and pumps; sight glasses; liquid level gauges; and extruded sheet, pipe, and film.

We do not recommend the use of Durethan[®] T 40 resin for those applications in which the part will be subjected to moisture at elevated temperatures because of hydrolysis can occur and cause degradation of the material resulting in part failure.

As with any product, use of Durethan[®] T 40 resin in a given application must be tested (including but not limited to field testing) in advance by the user to determine suitability.

Chemical Resistance

In general, Durethan[®] T 40 polyamide resin is resistant to hydrocarbons, such as fuels, oils and greases, esters, ketones, and organic and inorganic bases up to medium concentrations. Durethan[®] T 40 resin is also largely resistant to many halogenated hydrocarbons, such as carbon tetrachloride and freon. Chloroform and methylene chloride, however, cause severe swelling. Short-chain alcohols, such as ethanol and methanol, produce effects similar to that of water, while longer-chain alcohols have virtually no effect.

Durethan[®] polyamide resins possess limited resistance to acids in general and are soluble in strong mineral acids, such as sulfuric and formic. In addition, materials such as phenols and cresols also attack these resins.

Surface quality and molded-in stresses can greatly influence chemical resistance. Therefore, molding operations can affect the chemical resistance of Durethan[®] T 40 resin.

A study was conducted internally on Durethan[®] T 40 polyamide. Samples (50 x 6 x 4 mm) were immersed in various media at room temperature, unless otherwise specified, for a period of 12 months. The results are summarized in the table on the last page.

As in the case with any compatibility test, results are dependent on such variables as concentration, time, temperature, part design, and residual stresses. Compatibility testing should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions.

Biocompatibility

Durethan[®] T 40 resin 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. The ranges of tests under FDA-Modified ISO-10993, Part I “Biological Evaluation of Medical Devices” include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. ***ONLY THIS PRODUCT MAY BE CONSIDERED CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY.*** No “medical-grade” Product will be made available for sale until successful completion of the above testing by LANXESS.

Reground 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 Durethan® T 40, 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 may Durethan® T 40 be used in any implant applications (cosmetic, reconstructive or reproductive). Nor may Durethan® T 40 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 the FDA-Modified ISO 10993 tests.

The suitability of Durethan® 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 Durethan® 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

The sterilization method and the number of sterilization cycles a medical device made from Durethan® T 40 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.

Drying

Durethan® polyamide resins are supplied in moisture-tight packaging, dry and ready for processing. However, resin that has absorbed moisture (i.e., regrind, material in opened or damaged bags, and/or color concentrates) must be dried to a moisture content of less than 0.1% prior to processing, in order to optimize property performance and appearance in molded parts. A desiccant dehumidifying hopper dryer is recommended with a maximum dew point of 0°F (-18°C) and an inlet air temperature of 175°F (80°C). Higher drying temperatures could result in discoloration of resin and pigment systems and therefore should be avoided. Drying time depends on initial moisture content.

Processing

Durethan® T 40 resin can be molded on standard injection molding equipment. A fume ventilation hood above the screw area and/or good vitalization of the work space are recommended. Optimum properties are achieved by keeping the melt temperature between 535°-570°F (280°-300°). Melt temperatures above 570°F (300°C) can cause thermal degradation and loss of properties. For extrusion, barrel temperatures up to 590°F (310°C) may be used.

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	490°-500°F (255°-260°C)
Middle	500°-535°F (260°-280°C)
Front	535°-555°F (280°-290°C)
Nozzle	535°-555°F (280°-290°C)
Ideal Melt Temperature	535°-570°F (280°-300°C)
Mold Temperature	185°-205°F (85°-95°C)
Injection Pressure	17,000 psi
Hold Pressure	80% of Injection Pressure
Back Pressure	50-150 psi
Screw Speed	80-100 rpm
Injection Speed	Moderate to Fast
Cushion	1/8-1/4 in
Clamp	3-5 ton/in ²

Additional information on processing may be obtained by contacting a LANXESS Corporation technical service representative.

Regrind Usage

Where end-use requirements permit, up to 10% Durethan® resin regrind may be used with virgin material, provided that the material is kept free of contamination and is properly dried (see section on

Drying). Any regrind used must be generated from properly molded/extruded parts, sprues, runners, trimmings, and/or film. All regrind used must be clean, uncontaminated, and thoroughly blended with virgin resin prior to drying and processing. Under no circumstances should degraded, discolored, or contaminated material be used for regrind. Materials of this type should be discarded.

Improperly mixed and/or dried regrind may diminish the desired properties of Durethan[®] resin. It is critical that you test finished parts produced with any amount of regrind to ensure that your end-use performance requirements are fully met. Regulatory or testing organizations (e.g., UL) may have specific requirements limiting the allowable amount of regrind. Because third party regrind generally does not have traceable heat history, or offer any assurance that proper temperatures, conditions, and/or materials were used in processing, extreme caution must be exercised in buying and using regrind from third parties.

The use of regrind material should be avoided entirely in those applications where resin properties equivalent to virgin material are required, including but not limited to color quality, impact strength, resin purity, and/or load-bearing performance.

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Durethan® T 40 Resin Property	
		U.S. Conventional	SI Metric
General Specific Gravity Density Specific Volume Mold Shrinkage: Flow Direction Cross Direction Water Absorption, 0.125-in (3.2-mm) Thickness: 24-Hour Immersion Equilibrium, 73°F (23°C) In Air (50% RH) In Water	D 792 D 792 D 792 (LANXESS) D 570 (DIN 53495)	0.043 lb/in ³ 23.5 in ³ /lb 0.006 in/in 0.006 in/in	1.18 0.006 mm/mm 0.006 mm/mm 0.5% 2.0% 6.0%
Thermal Deflection Temperature, Unannealed: 0.157-in (4.0-mm) Thickness 264-psi (1.8-MPa) Load 66-psi (0.46-MPa) Load Relative Temperature Index: 0.030-in (0.75-mm) Thickness Electrical Mechanical with Impact Mechanical without Impact	D 648 (UL746B)	225°F 244°F 149°F 149°F 149°F	107°C 118°C 65°C 65°C 65°C
Flammability** UL94 Flame Class: 0.030-in (0.75-mm) Thickness 0.059-in (1.5-mm) Thickness 0.118-in (3.0-mm) Thickness	(UL94)		V-2 Rating ⁿ V-2 Rating ⁿ V-2 Rating ⁿ

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Durethan® T 40 Resin			
		Dry as Molded ^a		Conditioned ^b	
		U.S. Conventional	(SI Metric)	U.S. Conventional	(SI Metric)
Mechanical Tensile Stress at Yield Tensile Elongation at Break Tensile Modulus Flexural Strength Flexural Modulus Impact Strength, Notched Izod: 0.125-in (3.2-mm) Thickness 73°F (23°C) -40°F (-40°C)	D 638 D 638 D 638 D 790 D 790 D 256	9,400 lb/in ² 435,000 lb/in ² 21,800 lb/in ² 420,000 lb/in ²	65 MPa 55% 3.0 GPa 150 MPa 2.9 GPa	8,000 lb/in ² 478,000 lb/in ² 18,800 lb/in ² 478,000 lb/in ²	55 MPa >100% 3.3 GPa 130 MPa 3.3 GPa
Electrical Volume Resistivity (Tinfoil Electrodes) Surface Resistivity Dielectric Strength: 0.118-in (3.2-mm) Thickness	(IEC 93) (IEC 93) (IEC 243)	1.0 E+15 ohm-cm 1.0 E+15 ohm		1.0 E+16 ohm-cm 1.0 E+16 ohm	
		635 V/mil	25 kV/mm	711 V/mil	28 kV/mm

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

**Flammability results are based on small-scale laboratory tests for purposed of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.

^aDry as Molded refers to a moisture content less than 0.2% by weight.

^bConditioned refers to an equilibrium moisture content in a standard laboratory atmosphere of 73°F and 50% relative humidity.

ⁿ Natural color.

Chemical Resistance of Durethan® T 40 Transparent Amorphous Polyamide*

Media	Rating
Acetic Acid (5%)	0
Acetic Acid (Conc.)	-
Acetone	+
Ammonium Hydroxide (25%)	+
Aniline	-
Benzene	+
Benzyl Alcohol	-
Butyl Acetate	+
Carbon Tetrachloride	+
Chlorobenzene	+
Cooking Oil	+
Cyclohexane	+
Cyclohexanone	+
Decalin ^a	+
Diisopropylether	0
Dimethylformamide	-
Dioxane	0
Ethanol (25%)	0
Ethanol (Abs.)	-
Ethyl Acetate	+
Formaldehyde	0
Gasoline (Regular)	+
Gasoline (Super)	+
Glycerine	+
Glycol	0
Hydrochloric Acid (1%)	0
Hydrochloric Acid (10%)	-
Hydrochloric Acid (Conc.)	-
Isobutylamine	-
Isopropanol	-

Media	Rating
Ligroine	+
Lipid Solution	+
Lorol ^b C10	+
Methanol	-
Methylene Chloride	-
n-Butanol	-
n-Propanol	-
Nitric Acid (10%)	-
Nitric Acid (30%)	-
Nitrobenzene	+
Petroleum	+
Petroleum Ether 60/70	+
Phosphoric Acid (10%)	+
Phosphoric Acid (30%)	+
Potassium Hydroxide (10%)	+
Potassium Hydroxide (50%)	+
Pyridine	-
Sodium Hypochlorite Solution (0.5% Free Cl)	+
Sodium Hydroxide (50%)	+
Sulfuric Acid (10%)	+
Sulfuric Acid (Conc.)	-
Tetrahydrofuran	-
Toluene	+
Tributylamine	-
Trichloroethylene	+
Water at 104°F (40°C)	0
Water at 140°F (60°C)	-
Xylene	+

* Unless otherwise noted, all data were determined at 73° F (23° C).

+ Resistant

0 Limited Resistance

- Not Resistant

^a Decalin is a trademark of E.I. DuPont de Nemours & Co.

^b Lorol is a trademark of Henkel KGaA.

Health and Safety Information

Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling the LANXESS products mentioned in this publication. For materials mentioned which are not LANXESS products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be followed. Before working with any of these products, you must read and become familiar with the available information on their 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 LANXESS Corporation representative or contact the Product Safety and Regulatory Affairs Department at LANXESS.

Note: The information contained in this publication is current as of January 2007. Please contact LANXESS Corporation to determine if this publication has been revised.

LANXESS Corporation

111 RIDC Park West Drive • Pittsburgh, PA 15275 • Phone: 1-800-LANXESS • www.US.LANXESS.com

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 test our products, technical assistance and information to determine to your own satisfaction whether they 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. 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 patents covering any material or its use. No license is implied or in fact granted under the claims of any patent.