

Eastman Tritan™ copolyester

Accelerated aging in medical devices and packaging

Medical device manufacturers require materials to perform at the highest standards over an extended period of time, as many products may be stored up to 5 years before use. Material aging information is needed to ensure product integrity, satisfy current FDA validation requirements, and provide evidence of fitness for use over a product's life cycle. To decrease the time required for testing prior to device commercialization, manufacturers often perform accelerated-aging studies on the product/package combination. An important aspect of aging plastics is physical aging: the process by which physical properties of plastics can improve or deteriorate over time as a plastic is held in a specific temperature range below its glass transition temperature (T_g). It is important that these accelerated-aging studies be performed properly since each plastic material ages differently. This technical tip will provide guidelines for conducting accelerated-aging tests of Eastman Tritan™ copolyester.

General accelerated-physical-aging guidelines

- The ASTM F1980 standard guidelines or methodology for accelerated aging of sterile medical device resins is based on the following Arrhenius equation:

$$t_E = t_T * Q_{10}^{a(T-T_{RT})/10}$$

Where

t_E = Equivalent time at ambient temperature and 50% relative humidity

t_T = Accelerated-aging time

T = Accelerated-aging temperature, °C

T_{RT} = Ambient temperature, 23°C

Q_{10} = Accelerated-aging factor

$Q_{10} = 8$ for Eastman Tritan™ copolyester

$Q_{10} = 2$ for generic plastics

^a The ASTM guidelines suggest using a Q_{10} factor of 2 as a conservative estimate for aging the device. The guidelines also state that each material has a unique accelerated-aging factor (Q_{10}). Other Q_{10} factors can be used if they are derived from experimentation. Eastman has found through extensive experimentation that the Q_{10} factor for Eastman Tritan™ copolyester is 8.

- Recommended conditions for Eastman Tritan™ copolyester: Perform aging at 50°C and 50% relative humidity. At these conditions, 32 hours is equivalent to 1 year of actual aging at room temperature (23°C). Therefore, 160 hours of accelerated aging at these conditions is equivalent to 5 years of actual aging at room temperature (23°C).
- Plastic material aging is reset or returns to zero during molding.



Detailed description of accelerated physical aging

Physical aging is a process of molecular relaxation that occurs in all amorphous polymers held at a specific temperature range below their glass transition temperature. This process has been observed in a number of plastics including polyvinyl chloride (PVC), polystyrene, styrene-acrylonitrile (SAN), polycarbonate, and polyesters. When a polymer is rapidly cooled below its T_g (as occurs with all commercial melt processing techniques), it vitrifies into a nonequilibrium conformation with excess free volume. In an attempt to attain thermodynamic equilibrium, the chains rearrange themselves into a more dense structure, reducing the free volume of the system. Densification can change thermodynamic and mechanical properties (e.g., impact resistance) of the material, which can, in turn, directly affect the performance of the device. These changes in properties can be directly measured over time and correlated to the extent of aging.

It is often desirable to obtain information about the long-term performance of materials, in many cases over time periods much longer than can be directly measured in the lab under practical conditions. The principle of time-temperature superposition enables prediction of long-term properties of materials. According to this principle, changes in polymer properties that occur over a given period of time at one temperature are equivalent to motions that occur over a longer period of time at lower temperatures. In other words, elevated temperature acts as a multiplier for the rate of molecular motion. Because of time-temperature superposition, it is possible to generate data as a function of time at different temperatures and then shift the data together on one common master curve. Material performance, which would normally have to be measured directly over long periods of time (e.g., 5 years at room temperature), can be predicted through testing at elevated temperatures and accessible time periods (weeks and months).

Numerous experiments were performed at Eastman to determine the mechanical and thermal properties of Eastman Tritan™ copolyester as a function of aging time and temperature. Master curves were generated from the aging data using time-temperature superpositioning. Aging times for each aging temperature that provide equivalent material

properties, shown in the table, can be used to perform accelerated-aging experiments. In an accelerated-aging experiment, a molded article may be aged at an elevated temperature for a short period of time to simulate aging at a lower temperature (e.g., ambient temperature) for an extended period of time. For example, 4 hours at 60°C is equivalent to 32 hours at 50°C or nearly 8,800 hours at 23°C. Therefore, if one wanted to simulate the performance of a part after 10 years of life (87,600 hours) at 23°C, one should age the part at either 50°C for 320 hours or 60°C for 40 hours. This aging protocol will reasonably represent the lifetime of a typical Tritan copolyester application. Note that aging Tritan at higher temperatures for longer times is not generally recommended. For example, aging for 250 hours (10 days) at 60°C is equivalent to aging for 549,000 hours (63 years) at room temperature (23°C). Aging for this time or longer at 60°C may overage the material and provide a poor estimate of the long-term material performance.

Accelerated-physical-aging data

Aging temperature	Simulated age/accelerated-aging time (hours)						
	~ 100 years	~ 24 years	~ 16 years	~ 2 years	~ 12 months	~ 3 months	~ 1.6 weeks
23°C (74°F)	876,000	210,719	140,480	17,660	8,800	2195	274
30°C (86°F)	204,500	49,000	32,750	4,100	2,050	512	64
40°C (104°F)	25,500	6,150	4,100	512	256	64	8
50°C (122°F)	3,193	768	512	64	32	8	1
60°C (140°F)	400	96	64	8	4	1	—
70°C (158°F)	50	12	8	1	0.5	—	—
80°C (176°F)	6.2	1.5	1	—	—	—	—

Accelerated age testing of Eastman Tritan™ copolyester

Accelerated-aging studies of Eastman Tritan™ copolyester were performed using the guidelines and methodology outlined in this document. Based on this testing, the Q_{10} factor is 8. Furthermore, the data suggests that Tritan copolyester provides the required device integrity for a minimum of 5 years if the device is stored at room temperature under normal conditions, provided that good manufacturing practices are followed during product design, injection molding, and sterilization.

EASTMAN

The results of insight™

Eastman Chemical Company Corporate Headquarters

P.O. Box 431

Kingsport, TN 37662-5280 U.S.A.

U.S.A. and Canada, 800-EASTMAN (800-327-8626)

Other Locations, +(1) 423-229-2000

www.eastman.com/locations

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on 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.

© 2016 Eastman Chemical Company. Eastman brands referenced herein are trademarks of Eastman Chemical Company or one of its subsidiaries or are being used under license. The ® symbol denotes registered trademark status in the U.S.; marks may also be registered internationally. Non-Eastman brands referenced herein are trademarks of their respective owners.