

EASTMAN

Eastman **TRITAN™**
copolyester

Chemical compatibility
with hospital disinfectants
and oncology drugs



As compatibility becomes more complex, **one solution remains clear**

In the hospital environment, the need to mitigate infection risks and enhance patient safety and comfort has significantly increased the demand for higher-performing plastics with improved chemical resistance.

This demand presents itself in two forms:

- Heightened awareness of hospital-acquired infections (HAIs) has resulted in the increased use of medical disinfectants such as isopropyl alcohol, formaldehydes, peracetic acids, ammonium-based chemicals and others.
- In addition, pharmaceutical companies' continuous efforts to advance medicine for cancer treatment has led to the development of new pharmaceuticals and oncology drugs.

Exposure to many of these chemicals has been found to cause cracking, crazing, and hazing in certain plastics—and can lead to compromises in performance, product life, and safety of the device.

Eastman Tritan™ copolyester offers clear advantages.

This brochure presents results from screening studies measuring Tritan's chemical compatibility with various medical disinfectants, oncology drug carrier solvents, and actual oncology drugs—and compares its compatibility to typical clear thermoplastics used in fluid-path and drug-administering medical devices, such as polycarbonate and impact-modified styrenic polymers.

Eastman Tritan™ copolyesters are known for clarity before and after radiation sterilization as well as for toughness, low residual stresses, and enhanced chemical resistance. The data from the studies outlined here suggest that Tritan offers enhanced chemical compatibility compared with other clear thermoplastics. Studies are presented separately for resistance against:

- Various hospital disinfectants (Table 1)
- Various oncology drug carrier solvents (Table 2)
- Actual oncology drugs used in the emerging area of chemotherapy treatment (Table 3)



Comparing chemical compatibility of clear medical polymers

What is chemical compatibility?

Chemical compatibility, also commonly referred to as chemical resistance, is defined as the resistance to change in mechanical properties after exposure to a chemical under a well-defined set of conditions. Understanding chemical resistance is complex because observations are often dependent on the nature of chemical contact (composition or chemistry, time, and temperature) and the level and type of stress found in the part. For these reasons, testing of actual parts under realistic end-use conditions is always recommended. However, the tests discussed in this brochure are useful for making material comparisons or screening different plastics against various commonly used disinfectants and oncology drugs.

Details of test procedures

In these studies, a series of disinfectants, oncology drug carrier solvents, and actual oncology drugs were screened against common thermoplastics using the reverse side impact test. Lipids also were tested for completeness.

For example, in the first test (Table 1), flex bars (0.5" x 5" x 1/8") of each material with four replicates were exposed to various disinfectants for 24 hours while being held under 1.5% strain utilizing a constant strain jig. After exposure, the energy required to break the flex bars was measured by impacting with a pendulum hammer. Impact occurs on the reverse side of chemical contact to place the chemically exposed surface in tension. In general, higher-percent retention in impact energy demonstrates better chemical resistance.

Chemical resistance against various disinfectants

Chemical resistance testing results against various disinfectants are shown in Table 1. Eastman Tritan™ copolyesters show excellent chemical resistance to a variety of medical disinfectants, including the aggressive Virex® TB. Although high-flow polycarbonate (PC) has traditionally been used in thin-wall medical device applications, the results in Table 1 indicate that high-flow Tritan MX731 copolyester may present improved chemical resistance compared with high-flow PC. Phenolic disinfectant was aggressive toward all plastics tested.

Chemical resistance against oncology drug carriers

Due to poor solubility in aqueous solutions of the most active pharmaceutical ingredients in oncology drugs, various chemicals such as alcohols, triglycerides, polymeric surfactants (polyethylene glycol or polysorbate 80), dimethyl acetamide (DMAc), and/or DMSO are used as carrier solvents to help dissolve the drugs. As a result, the major component of the oncology drug formulation can be the carrier solvent. These solvents can be very aggressive to most thermoplastics and potentially lead to cracking and crazing. Medical device engineers must therefore carefully consider a material's chemical resistance to the carrier solvent when the device is expected to come in contact with oncology drugs. From a practical standpoint, testing carrier solvents may potentially reduce the cost and safety concerns of testing actual oncology drugs.

Chemical resistance against actual oncology drugs

Although it is very useful and convenient to evaluate a material's chemical compatibility with drug carrier solvents, it is also important to understand the chemical resistance to actual oncology drugs. Both Tritan MX711 and MX731 exhibit excellent chemical resistance to all six screened oncology drugs (Table 3) with the one exception of reduced resistance of MX731 to Taxol®, which also interacts strongly with both standard and high-flow PC and IM-styrenic material. High-flow PC displays low-impact property retention when exposed to etoposide, ifosfamide (IFEX), and methotrexate. All materials were observed to have good chemical resistance toward cyclophosphamide.

Eastman Tritan™ copolyesters can be compatible with initiatives to manufacture medical devices and parts without bisphenol A (BPA). Tritan provides a BPA-free solution for brand owners, health-care providers and patients who value this option.

Table 1 Retention of impact energy to break (%) against various disinfectants

Material	Control (Joules)	Lipids	IPA	Bleach	4% Formaldehyde	Cidexplus®	Cidex® OPA	3% Paracetic acid	4% Renalin	Quat	Phenolic	Virex® TB	3% Hydrogen peroxide
		% Retention in properties											
Eastman Tritan™ copolyester MX711 (standard)	4.4	87 ± 2	80 ± 2	92 ± 2	92 ± 2	94 ± 2	95 ± 4	96 ± 3	97 ± 4	86 ± 1	8 ± 1	75 ± 26	95 ± 3
Tritan MX731 (high-flow)	4.3	90 ± 1	87 ± 4	94 ± 1	98 ± 4	95 ± 1	96 ± 1	100 ± 5	100 ± 3	95 ± 4	8 ± 4	65 ± 24	96 ± 3
PC (standard)	5.4	92 ± 5	85 ± 18	104 ± 4	112 ± 1	104 ± 3	105 ± 5	108 ± 1	108 ± 1	101 ± 6	30 ^b	All broke on jig	110 ± 2
PC (high-flow)	5.3	53 ± 49	22 ± 3	78 ± 52 ^a	112 ± 1	82 ± 44	105 ± 4	110 ± 3	110 ± 3	83 ± 29	50 ^b	All broke on jig	104 ± 1

Table 2 Retention of impact energy to break (%) against various oncology drug carrier solvents

Material	Control (Joules)	MCT oil ^a	Etoposide carrier solvent ^b	Busulfex® carrier solvent ^c	Dimethylacetamide	Dimethylsulfoxide
Eastman Tritan™ copolyester MX711 (standard)	4.4	68 ± 13	90 ± 2	79 ± 6	63 ± 35	84 ± 2
Tritan MX731 (high-flow)	4.3	33 ± 2	78 ± 23	39 ± 8	25 ± 15	60 ± 7
PC (high-flow)	5.3	7 ^f	All broke on jig	All broke on jig	All broke on jig	All broke on jig
PC (standard)	5.4	34	12 ± 1	All broke on jig	All broke on jig	All broke on jig
PC (lipid-resistant)	5.5	47 ± 52	28 ± 42	All broke on jig	All broke on jig	All broke on jig
Impact modified styrenic	4.3	10 ± 1	7 ^e	8 ± 1 ^d	Severe surface attack	9 ^e

^aMCT oil: medium chain triglycerides oil.

^bEtoposide carrier solvent: 10 mL of the solvent mix contains 3.05 mL ethanol, 6.5 g of polyethylene glycol 300, 0.8 g polysorbate 80, 0.33 g benzyl alcohol and 20 mg citric acid.

^cBusulfex injection carrier solvent: 10 mL of the solvent mix contains 3.3 mL dimethylacetamide and 6.7 mL polyethylene glycol 400.

^d1 of 4 samples broke on jig.

^e2 of 4 samples broke on jig. Standard deviation not calculated.

^f3 or 4 samples broke on jig. Standard deviation not calculated.

Table 3 Retention of impact energy to break (%) against actual oncology drugs

Material	Control (Joules)	Taxol ^a	Etoposide ^b	IFEX ^c	Methotrexate ^d	Cyclophosphamide ^e	Adriamycin ^{®f}
Eastman Tritan™ copolyester MX711 (standard)	4.4	80 ± 4	84 ± 2	91 ± 1	103 ± 1	105 ± 1	94 ± 4
Tritan MX731 (high-flow)	4.3	46 ± 1	87 ± 5	96 ± 3	105 ± 1	95 ± 2	107 ± 2
PC (high-flow)	5.3	All broke on jig	48 ± 46	28 ± 43	54 ± 58	104 ± 2	101 ± 11
PC (standard)	5.4	12 ^g	66 ± 44	87 ± 41	101 ± 1	114 ± 2	104 ± 3
PC (lipid-resistant)	5.5	43 ± 42	76 ± 34	94 ± 9	77 ± 41	109 ± 2	113 ± 2
Impact modified styrenic	4.3	All broke on jig	4 ± 1	9 ± 1	100 ± 1	100 ± 1	10 ± 2

^aTaxol: each mL of sterile nonpyrogenic solution contains 6 mg paclitaxel, 527 mg polyoxyl 35 castor oil, 49.7% v/v dehydrated alcohol, USP, and 2 mg citric acid USP.

^bEtoposide: each mL solution contains 20 mg etoposide, 2 mg citric acid, 30 mg benzyl alcohol, 80 mg polysorbate 80, 650 mg of polyethylene glycol 300, and 30.5% (v/v) alcohol.

^cIFEX: each mL solution contains 50 mg ifosfamide and 0.9% w/v sodium chloride USP.

^dMethotrexate: each mL solution contains 25 mg methotrexate, 0.9% w/v benzyl alcohol, and 0.26% w/v sodium chloride USP.

^eCyclophosphamide: each mL testing solution contains 10 mg of cyclophosphamide, 0.9% w/v sodium chloride.

^fAdriamycin: each mL testing solution contains 1 mg doxorubicin hydrochloride, USP, 5 mg lactose monohydrate, and 0.9% w/v sodium chloride USP.

^g2 of 4 samples broke on jig. Standard deviation was not calculated.

KEY

- Good retention of impact energy
- Significant decrease in impact energy
- Severe decrease in impact energy
- Significant plasticization (absorption and swelling)

In the tables above, one standard deviation (±) is reported. Samples that broke the jig are not included in average of standard deviation.

Summary

The screening tests discussed in this brochure indicate Eastman Tritan™ copolyesters exhibit good chemical compatibility over other commonly used clear thermoplastics. However, when evaluating the chemical resistance of materials, it is also important to consider a material's residual stress (as well as any applied stress during real use) and toughness (tensile and impact strength). Residual stresses from material processing are well-known to impact part performance due to potential crazing caused by a combination of stresses and chemical exposure.

A layer removal technique shows that Tritan has 0.2 to 0.5X lower residual stress after the molding process than PC.¹ For this reason, it generally shows excellent chemical resistance performance in market applications where PC suffers from cracking and crazing (See Figure 1). Toughness is also important because it directly influences if a craze will turn into a crack, potentially leading to catastrophic failure. The results of this screening study plus residual stress and toughness considerations are summarized in Table 4. These studies suggest that Tritan is an ideal candidate for medical device applications where exposure to medical disinfectants or aggressive chemotherapy drugs are expected.

Table 4 **Relative comparison of typical clear thermoplastics used in the medical market**

Property center	Eastman Tritan™ copolyester	Polycarbonate	Impact-modified styrenics
Residual stress	Low	High	Untested
Toughness	High	High	Low
Chemical compatibility under stress	High	Moderate to low	Low
Overall chemical resistance	High	Medium	Low

Figure 1 **Medical device housing after exposure to Virex TB**



The PC housing on the left shows a significant crack (visible in circled area) after eight hours of exposure, indicating chemical attack due to high residual and molded-in stress in the part. The housing on the right, molded with Tritan, has not cracked after 120 hours of exposure.

Reliable results for oncology drug therapy components

In addition to excellent chemical compatibility, Eastman Tritan™ copolyester offers:

- **Excellent clarity**—before and after non-autoclave sterilization methods such as gamma or electron beam (e-beam) radiation.
- **BPA-free**—Tritan is also not manufactured with BPA or halogens (chlorine, bromine) and is not manufactured with *ortho*-phthalates
- **Enhanced heat resistance**—relative to heritage copolyesters
- **Secondary operations**—Compatible with a wide variety of manufacturing and assembly operations
- **Extreme toughness and durability**—impact and shatter resistance plus low residual stress

For more information about Eastman Tritan™ copolyester and its chemical compatibility for the medical market, visit www.eastman.com/medical or call 1-800-EASTMAN (800-327-8626).

¹Treece MA, Stack GM. Residual Stress Evaluation of Eastman Tritan™ Copolyester, Polycarbonate and Their Blends, With ABS. Plast Eng (ANTEC). May 2011.



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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.

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