EASTMAN

Chemical compatibility with hospital disinfectants and oncology drugs

As compatibility becomes more complex, one solution remains clear.

Eastman **TRITAN**™
copolyester

In a 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, and ammonium-based chemicals.
>
> • 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 chemotherapy treatment (Table 3)

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

		Lipids	IPA	Bleach	4% formaldehyde	CidexPlus®	Cidex® OPA	3% peracetic acid	4% Renalin™	Quat	Phenolic	Virex® TB	3% hydrogen peroxide
Material	**Control (joules)**	**% retention in properties**											
Tritan 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	All broke on jig	110 ± 2
PC (high flow)	5.3	53 ± 49	22 ± 3	78 ± 52	112 ± 1	82 ± 44	105 ± 4	110 ± 3	110 ± 3	83 ± 29	50	All broke on jig	104 ± 1

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

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	Dimethyl sulfoxide
Tritan 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[d]	All broke on jig	All broke on jig	All broke on jig	All broke on jig
PC (standard)	5.4	34[e]	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[f]	Severe surface attack	9[e]

[a]*MCT oil: medium-chain triglycerides oil*
[b]*Etoposide 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.*
[c]*Busulfex injection carrier solvent: 10 mL of the solvent mix contains 3.3 mL dimethylacetamide and 6.7 mL polyethylene glycol 400.*
[d]*Three of four samples broke on jig. Standard deviation not calculated.*
[e]*Two of four samples broke on jig. Standard deviation not calculated.*
[f]*One of four samples broke on jig.*

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]
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	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

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

[a]*Taxol: 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.*
[b]*Etoposide: 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.*
[c]*IFEX: Each mL solution contains 50 mg ifosfamide and 0.9% w/v sodium chloride USP.*
[d]*Methotrexate: Each mL solution contains 25 mg methotrexate, 0.9% w/v benzyl alcohol, and 0.26% w/v sodium chloride USP.*
[e]*Cyclophosphamide: Each mL testing solution contains 10 mg of cyclophosphamide, 0.9% w/v sodium chloride.*
[f]*Adriamycin: Each mL testing solution contains 1 mg doxorubicin hydrochloride, USP, 5 mg lactose monohydrate, and 0.9% w/v sodium chloride USP.*

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 $\frac{1}{8}$ in.) 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. Tritan shows 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 one exception of reduced resistance of Tritan 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.

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

Summary

The screening tests discussed in this brochure indicate that Tritan exhibits good chemical compatibility compared to 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 0.5 times 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 is expected.

[1]*Treece M.A.; Stack, G.M. Residual Stress Evaluation of Eastman Tritan Copolyester, Polycarbonate and Their Blends, With ABS. Plast. Eng. (ANTEC). May 2011.*

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	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, Tritan offers:

- Excellent clarity—before and after non-autoclave sterilization methods such as gamma or electron-beam (e-beam) radiation
- BPA-free—Tritan is 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 eastman.com/medical or call 1-800-EASTMAN (800-327-8626).

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The results of **insight**™

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